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June 16, 2005

DRG (Stukos) Hefler Hartstein Brooks Fagan Gruber Kelly Hue

Mr. Marc Hartstein
Deputy Director of the Division of Acute Care
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Room C4-25-11
Mail Stop C4-03-06
Baltimore, MD 21244-1850

RE: Stroke – DRG 14 / 15

Dear Marc:

On behalf of my colleagues Drs Lawrence Brass, Walter Koroshetz as well as the American Academy of Neurology and Brain Attack Coalition, we want to thank you and your colleagues at CMS for being receptive to our proposal on modifying reimbursement of medical therapies administered to stroke patients as it relates to DRGs 14 and 15.

As we shared with you during our meeting on March 15th, Stroke is a devastating disease that affects more than 750,000 people annually in the United States, and as you are aware, costs the US medical system more than $52 billion annually in post-acute care. The administration of reperfusion therapies has been proven to reduce the devastating consequences of severe stroke if administered to the patient within the 3 hour window and substantially decreases the costs of post-acute stroke care.

There is much to be done to improve stroke outcomes including stroke prevention, continuing education for physicians as well as patients, and development of new therapies. All of these aspects of improving stroke care are being gradually addressed through physician education by medical societies, patient education by societies such as the American Stroke Association and National Stroke Association, as well as development and testing of new therapies by researchers and industry.

CMS can make a substantial positive impact on stroke care and reduce the long-term post-acute care costs to Medicare by removing some of the financial disincentives that exist within the current DRGs 14 and 15 as demonstrated in our past presentations.

As discussed in March, we envision two possible ways of affecting change: 1) Redefining the current DRGs 14 and 15 whereby one would be specific to the administration of reperfusion therapies or preferably 2) Creating a new DRG for the administration of reperfusion therapies.

CMS acknowledged our proposal through the Proposed Rule, published in April 2005. In the Proposed Rule, under reporting of thrombolytic administration in the MedPAR database was a primary concern and CMS requested data to address this issue and sought input from the public on the proposals.

To that end, we have worked to collect additional data that demonstrates a higher administration of thrombolytic therapy than is suggested within ICD-9 code 99.10 in the MedPAR database.

Our submitted and attached data come from 3 principal sources: the Premier Perspective database dating back to 2001, the Center for Disease Control sponsored Coverdell Registry from four states during 2001 published in the journal Stroke, and thrombolytic administration data from stroke centers throughout the U.S. All of the data demonstrate clearly that thrombolytics are administered more than twice as often as are coded under ICD-9 code 99.10. Even taking the most conservative estimate (Premier Database), these data indicate that at least 6,000 MEDICARE patients with a stroke are treated with thrombolytics each year.

Based on conversations with members of the stroke community, we believe that the under reporting of thrombolytic administration is primarily due to the fact that ICD-9 code 99.10 does not have any DRG determining effect. A change in reimbursement such as we have proposed could help address this situation.

To give you a sense of the quality of the data being submitted, the following are descriptions of the Premier database and the Coverdell Registry.

> Premier's database is a large hospital drug utilization and financial database. Information is available from over 500 acute care facilities and includes approximately 22 million inpatient records. On an annual basis, this constitutes roughly one out of every six inpatient discharges in the United States. Data are available from January 2000 through the present, but have a lag time of approximately six months. Premier's primary mission is to assist health care institutions improve clinical and operating performance in three strategic areas: group purchasing, supply chain and healthcare informatics. To that end, the Premier Informatics group developed this database in part to analyze utilization of resources to improve clinical efficiency.
>
> The hospitals that contribute information to this database are a select sample of both Premier and U.S. institutions, and do not necessarily represent all hospitals in the U.S. Data are collected from this sample of participating hospitals with diverse characteristics based upon geographic location, bed size, population served, payors and teaching status. The data collected include demographic and pharmacy-billing information, as well as all diagnoses and procedures for every patient discharge. Preliminary comparisons between participating Premier hospital and patient characteristics and those of the probability sample of hospitals and patients selected for the National Hospital Discharge Survey (NHDS) proved to be very similar with regard to patient age, gender, length of stay, mortality, primary discharge diagnosis and primary procedure groups.
>
> The Coverdell Registry is a National Acute Stroke Registry sponsored by the Centers for Disease Control and Prevention. Its goal is to monitor the practice of evidence-based medicine for acute stroke patients and target opportunities for improvements in quality care for stroke patients. As part of this registry, administration of thrombolytic therapy was tracked and the findings are included below.

Separately, we asked the National Stroke Association and their Stroke Center members to contribute information pertaining to their thrombolytic experience. With a sampling of 20 hospitals across the United States, one can see that thrombolytic therapies are administered more than 2 to 3 times as often as is suggested in the MedPAR database.

The data from all of these sources are summarized for you below:

MedPAR Data				
	FY 2001	**FY 2002**	**FY 2003**	**FY2004**
Total Number of Cases in DRGs 14 and 15	474,366	472,900	324,339	293,214
# Receiving a Thrombolytic and Coded w/99.10	2,527	2,483	2,454	2,448
% Treated	**0.53%**	**0.53%**	**0.76%**	**0.83%**

Premier Database				
	FY 2001	**FY 2002**	**FY 2003**	**FY2004**
Total Number of Cases in DRGs 14 and 15	58,460	63,406	43,435	39,764
# Receiving a Thrombolytic and Coded w/99.10	378	413	388	420
% Treated	**0.65%**	**0.65%**	**0.89%**	**1.06%**
Total Actual Utilization of a Thrombolytic from Pharmacy Records	716	816	781	836
% Treated	**1.22%**	**1.29%**	**1.80%**	**2.10%**

National Stroke Association - Stroke Center Hospitals*				
	FY 2001	**FY 2002**	**FY 2003**	**FY2004**
Total 14/15 Cases	5,407	6,541	6,756	6,691
Use of ICD-9 Code 99.10 for Treating Patients Assigned to DRG 14 & 15	117	144	118	209
% Treated	**2.16%**	**2.20%**	**1.75%**	**3.12%**
Actual Lytic Use in DRG 14 & 15 Cases based on Pharmacy Records	114	172	197	288
% Treated	**2.11%**	**2.63%**	**2.92%**	**4.30%**

* Not all hospitals could provide complete data going all the way back to 2001. Raw data is supplied in the appendix.

Coverdell Registry					
	GA	**MA**	**MI**	**OH**	**Total**
Number of total ischemic stroke patients	921	709	1,584	1,066	4,280
IV/IA treated patients	22	57	38	33	150
% treated	2.4%	8.0%	2.4%	3.1%	3.7%

A change in reimbursement by CMS would be a very important and meaningful step in improving care for stroke patients.

In closing, we would like to thank you for the work that you continue to do on behalf of Medicare beneficiaries. We also appreciate your open dialogue with us regarding this opportunity to make a difference for stroke patients and welcome the opportunity to work with you again in the future.

Please contact any of us if you have questions about the information that we have provided to you.

Warm regards,

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University of Cincinnati

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cc:

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1500-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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Heather Hartstein

DRG/GEN - Brooks
Fagan
Gruber
Kelly
Hue

Sutter Medical Center, Sacramento

A Sutter Health Affiliate

June 14, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1500–P
P.O. Box 8011
Baltimore, MD 21244–1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and fiscal year 2006 Rates

Dear Sir:

Sutter Medical Center Sacramento, Medicare Provider #050108, is a 600-bed acute care multi-campus facility located in Sacramento, CA. As a major health care provider for Cardiac services in our area, the Medical Center physicians implant medical devices and perform other procedures on a significant number of Medicare beneficiaries, in the inpatient setting. Because inpatient services are a key component of what we provide, We are writing to express our concern with the proposed rule, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates," published by the Centers for Medicare and Medicaid Services (CMS) on April 25, 2005. Our concern is on page 50 of the proposed rule where CMS proposes to modify the DRGs for ICD implants. DRG

On page 50 of the proposed rule CMS provides an analysis showing the three ICD DRGs with and without hospital procedure code 37.26. The problem with the analysis is hospital procedure code 37.26 contains three separate procedures, of varying intensity: electrophysiology study, intra-operative device implantation and non-invasive programmed stimulation. This means code 37.26 represents a coding disparity (three very different codes in one), which is reflective in the intensity of services provided; not a payment problem. Until the coding issue is addressed, the real impact on payment cannot be determined. Currently there is no data on how the three procedures vary with respect to hospital charges. In a meeting attended by industry, CMS coding experts acknowledged that the structure of hospital procedure code 37.26 results in flawed charge data.

The payment change CMS proposes would have a severe financial impact on the hospital – without data to justify the change. This is particularly true for CRT-D devices, which are ICDs that addresses both Sudden Cardiac Death and heart failure and represent a higher acquisition cost than single purpose ICDs.

CMS says it's not appropriate to have all three procedures in code 37.26 drive to higher paying DRGs. It's equally inappropriate to have all three drive to lower paying DRGs.

We respectfully request that CMS withdraw the proposed ICD DRG revision and address this coding problem, with an appropriate coding solution, before attempting to make detrimental changes to the current defibrillator DRG structure that will seriously impact the hospital financially and potentially harm patient outcomes.

Sutter Medical Center Sacramento is willing to work with CMS and industry to appropriately identify codes that will support the hospital's goal of providing services to patient that cover cost and yet do not impact CMS' desire to pay appropriately for beneficiary care.

Thank you for your consideration.

Sincerely,

Margaret Mette

Margaret Mette
Assistant Administrator
Sutter Medical Center Sacramento

F Junod, M.D.

Forrest Junod, M.D.
Medical Director
Sutter Heart Institute
Sutter Medical Center Sacramento

UNIVERSITY of HARTFORD

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RECEIVED
JUN 21 2005
BY:

June 13, 2005

Walter Harrison
President

TRANS – WALZ
HART
DRG/GEN – BROOKS
FAGAN
GRUBER
KELLY
HUE

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500 – P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Post-acute Care Transfers; Proposed Changes to the Hospital Inpatient Prospective Payment System and FY'06 Rates; Proposed Rule

Dear Administrator McClellan:

I write as a Director of the St. Francis Hospital and Medical Center. I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) draft rule on the Medicare Hospital Inpatient Prospective Payment System, as published in the May 4, 2005 *Federal Register*. We are particularly concerned about CMS' reported request to expand the number of DRGs subject to the post-acute transfer policy from the current 30 to 223.

TRANS
DRG

The current Medicare transfer payment policy requires that cases assigned to one of 30 DRGs be paid as *transfers* when patients are discharged to psychiatric or rehabilitation hospitals or units, children's, long-term care, or cancer hospitals, and skilled nursing facilities or home health agencies. Under this policy, payment is *per diem*.

I strongly oppose expanding the transfer policy to encompass additional classes of patient cases. We believe this would fundamentally weaken the incentives inherent in the inpatient PPS. A new transfer policy covering 223 DRGs would effectively uproot an incentive-based system fueled by per-case control, to one inordinately focused on per diem costs.

Again, we are opposed to any expansion of the inpatient transfer policy, and believe that such a move would most assuredly not be in the best interests of patients or providers. The proposed policy would undermine clinical decision-making and penalize hospitals for providing patients with the most appropriate care in the most appropriate settings.

Thank you for this opportunity to comment on the proposed inpatient PPS rule.

Sincerely,

Walter Harrison

Walter Harrison
President

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CAH/Reloc

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Hatch
Hartstein
Collins
Nancy
Smith

Attachment #175
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
PO Box 8011
Baltimore, MD 21244-1850

June 7, 2005

Reference: CMS-1500-P

Via e-mail: **cms.hhs.gov/regulations/ecomments**
"Critical Access Hospitals"

To Whom It May Concern:

Comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that have been designated as a Necessary Provider (NP).

I am writing as Director of the Oklahoma Office of Rural Health and on behalf of rural residents of Oklahoma.

A recent proposed rule (Inpatient PPS) from the Centers for Medicare and Medicaid Services (CMS) provides that any Critical Access Hospital (CAH) designated as a "necessary provider (NP)" by the State is prohibited from building a replacement facility unless: (1) It's within 250 yards or on land owned before 12/08/03, (2) construction plans were started before 12/08/03, and (3) the new facility will provide care to at least 75% of current patients using at least 75% of existing staff (75% rule). The penalty for violating these regulations is an automatic loss of both CAH certification and cost-based reimbursement. Over 50% (600) of all CAH's are "necessary providers".

CMS has taken an ill advised step which will result in rural communities being unable to obtain quality medical care. The proposed regulations are a broad over-reach of CMS authority and place a ban on new construction for almost half of all small rural hospitals in the United States. This is problematic for the following reasons:

It was not the intent of Congress that CMS would prohibit or hinder communities from replacing facilities that provide quality health care to rural America. Many of the small hospitals in the rural United States were financed under the Hill-Burton act and are now

forty to fifty years old. These aging facilities are simply not capable of providing high quality, cost efficient service without the Necessary Provider Designation. One of the

primary reasons for this situation is the Prospective Payment System (PPS) adopted by CMS formerly HCFA almost twenty-five years ago. As an Office of Rural Health, we have long held that this system has unfairly penalized low volume providers. Furthermore, the PPS has meant that many rural hospitals have not been able to adequately fund depreciation expenses over a long period of time. These measures and rules have already had the effect of nearly guaranteeing these facilities no longer have the capacity for capital expenditures sufficient to replace most rural hospitals. As a result, rural hospitals have not been able to keep up with their urban and suburban counterparts who were increasingly paid more for the same service than rural hospitals. Rural hospitals also have the burden of a much larger percentage of Medicare population than urban hospitals. Thus, every tweak in the PPS system fell more heavily on rural hospitals because of this fact.

The CMS proposed regulations are an over-reach to a potential problem that can be easily managed without placing a ban on all new construction. Many CAHs are located on either small campuses or on campuses that adequately served the rural community population decades ago. CMS fails to understand that rural communities have changed and that the current hospital location and physical plant may not adequately meet the community's needs. These decisions allow for superior service and access and are not a means to compete against PPS facilities. To assume differently is to grossly misunderstand rural America, something that CMS has obviously done. To do so would attribute urban faults to rural hospitals. If in fact the situation would arise that the CAH moved just to have a more competitive advantage over a rival PPS hospital, the 75% rule would prevent that from happening. CMS has consistently failed to understand the safety net nature of rural hospitals and rural doctors. This is especially important for Medicare beneficiaries that many times have no where else available for comprehensive healthcare services. This outlook shows an inadequate knowledge of rural America and an extreme bias against a congressionally mandated cost-based reimbursement for Critical Access Hospitals.

CMS cost estimates in the proposed rule are simply incorrect. CMS assertion these hospitals will cost an average of $25M to $35M does not stand up in the real world. One recent real world example is the recently completed CAH in Drumright, Oklahoma. A fifteen bed hospital with two complete surgical suites, this new state-of-the-art facility cost $7.5M. This discounts the donation of land on which the hospital is constructed. Of this cost, $2.1M was for new equipment. This means that a 36,000 square foot state-of-the-art facility costs $5.4M. While this does not represent current building costs all across the country, it is certainly as valid as the $25M to $35M estimate used by CMS.

The proposed rule will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care. As inefficiencies are realized, CMS will be forced to provide more money to assets to maintain an aging and declining healthcare infrastructure in rural America. Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare more over time, not less. The higher labor costs of operating in a retrofitted building more than offset the slightly cost of rebuilding. The proposal then displays a

short sighted thinking process by the rule makers and a dramatic misunderstanding of the health care setting in rural areas.

The CMS proposed ban on construction is based on its bias against cost based reimbursement rather than on any established fact. CAHs in so far as replacement and/or relocation should be treated as any other hospital by CMS. This "difference" is not based in law but rather in CMS bias against small rural hospitals and cost based reimbursement. The proposed ban on major construction projects developed after December 8, 2003 is an over reaction against a potential problem that can be appropriately managed with current CMS policy. As mentioned earlier we support the long-standing 75% rule that simply states that if a hospital relocates, it must serve 75% of the same community as previously served to be considered the same provider. We think this alone would solve the grossly exaggerated claim that most CAHs want to move to be in a more competitive position with their nearest PPS competitor. Second, CMS seems to be in a panic mode concerning the growth of the CAH program. This was specifically intended by Congress. The growth of the program is limited by the number of rural hospitals that reasonable have twenty-five or fewer beds. Every reasonable estimate puts this potential universe at less than 1500 hospitals nation-wide. Since more that 1100 hospitals have already converted to CAH status. That leaves less than 400 hospitals even potentially eligible for this designation. Attention should be paid to the total cost of the program (approximately $3B annually) and the additional cost as compared with all these CAHs being PPS hospitals (less than $800M according to MedPac figures) compared with the total hospital budget this year for CMS of better than $239B. This makes the total CAH expenditure less than 0.01% of the total annual CMS hospital budget. In this context the argument becomes one that is philosophical rather than substantive. Obviously, CMS does not favor cost-based reimbursement even though it is mandated by Congress. This Congressional mandate is fostered by the abject failure of the current PPS payment system to adequately reimburse rural hospitals for vital health services provided to Medicare beneficiaries.

The CMS proposed regulations reverse a long standing policy. Designation as a CAH necessary provider is associated with its current Medicare provider agreement which should remain intact unless the CAH fundamentally changes its business or is terminated by Medicare for cause. It is a longstanding policy that the provider agreement describes the legal entity and the services provided – not the physical structure or location. It should also be noted that CMS was required to approve each state's plan for designating necessary providers. Because of the constant change in health care, this plan should be revisited by both the state and CMS on a regular basis, probably every three to five years.

Finally, this proposed rule transfers to CMS control over local rural health care never envisioned by Congress. This change would be a loss of local and state control never seen before. If allowed to stand, it would be a threat to all hospitals and all communities, small and large. This change would give CMS unprecedented authority to dictate the structure of local health systems and control access to health care. This constitutes an unnecessary intrusion into the economic development of rural communities. If allowed to go into effect this rule would do significant harm to rural America's healthcare system,

bring to bear unforeseen strain on the country's urban healthcare system and establishes a precedent of regulatory intrusion directly counter to the intent of Congress.

Based on the information presented above, our recommendation is that any CAH be allowed to replace or relocate their facility and maintain their status as a CAH as long as that facility can satisfy the 75% rule. We support the 75% rule that simply states that when a hospital relocates it will be servicing the same community and will be operating essentially the same services with essentially the same staff. We think this alone would solve the grossly exaggerated claim that most CAHs want to move to be in a more competitive position with their nearest PPS competitor.

Specifically, we absolutely oppose any and all deadlines for actions related to Critical Access Hospital (CAH) replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule. The proposed "75% threshold" is appropriate and sufficient to assure that a replacement or relocation CAH facility continues to meet the intent of its original Necessary Provider designation, i.e. that the "CAH serves at least 75 percent of the same service area that it served prior to its relocation, provides at least 75 percent of the same services that it provided prior to the relocation, and is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees."

Sincerely,

Val Schott, MPH, Director
Oklahoma Office of Rural Health

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Submitter : Mr. James Kirkpatrick

Date: 06/07/2005

Organization : Massachusetts Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Issue Area: Geographic Reclassification

CMS-1500-P-174-Attach-1.DOC

CMS-1500-P-174-Attach-2.DOC

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Gen Reclass
WI/Gen Update

Hefter
Hartstein
Kealey
Miller

MHA

Massachusetts Hospital Association

Attachment #174
June 7, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: CMS-1500-P; Medicare Program, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

The Massachusetts Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to comment on the proposed rule for the FY 2006 Inpatient Prospective Payment System (IPPS). We are writing to seek clarification from the Centers for Medicare & Medicaid Services (CMS) regarding portions of the FY 2005 Medicare inpatient PPS regulation that affected the ability of selected Massachusetts hospitals to secure reclassification for Medicare wage index purposes. We also ask CMS to make any adjustments in the FY 2006 Medicare inpatient PPS regulation that may be needed to address any inequities that may have resulted because of how the FY 2005 regulation may have been interpreted or applied inappropriately.

Specifically, we ask CMS to include in the final version of the FY 2006 Medicare inpatient PPS regulation:

1. Clarification that qualification for area wage reclassification based on the 1990 census proximity standard using CMSAs also include New England County Metropolitan Areas (NECMAs) for New England hospitals.
2. Provision for an expedited process for the hospitals of Bristol County, Massachusetts to reclassify into the Boston wage index area for FFY 2006-2008.
3. Rejection of the proposed FY 2006 Medicare inpatient PPS rule change to eliminate the 1990 proximity standard as grounds for allowing a hospital to reclassify for Medicare wage index purposes.

The Current Situation:
The hospitals of Bristol County, Massachusetts were classified in the Boston Wage Area (New England County Metropolitan Area or NECMA) for Medicare wage index purposes for more than a decade until 2005 when they were redesignated into the Providence/Fall River Wage Area or Core-Based Statistical Area (CBSA). Working together, the hospitals applied for a county-wide reclassification into the new Boston/Quincy wage index area. Their application and subsequent appeal were denied because they supposedly failed to meet the proximity requirement. It is clear, however, that if the demographic conditions found in this situation had arisen anywhere in the country except in New England, the applicant hospitals would have been found to be in compliance with the proximity requirement and their request would have been approved.

The Case for Reclassification:
The stakes in this issue are considerable: Failure to reclassify will mean a loss of somewhere between several hundred thousand dollars and more than a million dollars in annual Medicare revenue for each of the hospitals of Bristol County. The loss of Medicare revenue means that these hospitals must compete for health care professionals seeking Boston wages but that they must do so without Boston resources. This is a competition they

cannot win. These hospitals will suffer significant financial harm – harm that also could affect the delivery of care.

The classification of Bristol County hospitals into the Providence/Fall River CBSA is based on the assumption that Bristol County is more a part of the life of the Providence area than it is a part of the life of the Boston area.

In reality, Bristol County is far more integrated with the Boston area than with the Providence area:

- Of the more than 250,000 working adults who live in Bristol County, more than twice as many – 22.1 percent – commute to work in Boston as commute to work in Providence (only 8.5 percent).
- Analysis of commuting data provided by the Bureau of Economic Analysis (the same data used by the Census Bureau to determine the out-commute adjustment) shows that nearly 27% of the *hospital workers* that reside in Bristol County commute to other Massachusetts counties (the vast majority to the Boston-Quincy wage area) while only 14% commute to Rhode Island. We submit that the existence of a *nearly double* rate of commuting indicates a tighter relationship between Bristol County and the Boston-Quincy healthcare labor market areas and a greater willingness/ability of the Bristol County pool of hospital workers to commute to such higher wage Massachusetts counties.
- An informal survey of the three hospitals in Bristol County shows that they derive the majority of their hospital workers from the Massachusetts labor pool. The weighted average percentage of employees that live in Rhode Island and work in Bristol County is only 15.5% while the remaining 84.5% of workers are from the Massachusetts labor pool.

The expiration of the 50/50 hold harmless provision that is propping up the Bristol County wage index in 2005 will lead to increasingly-lopsided competition in the Massachusetts labor pool while further eroding the ability of Bristol county hospitals to pay the wages to attract and retain workers and will threaten the hospitals' long term viability. It is essential to recognize that Massachusetts is a small state with relatively short driving distances and the existence of the *artificial* boundary that separates the Bristol County wage area from its Massachusetts neighbors decreases Bristol County hospitals' ability to compete in their very real labor market.

Basis for Rejection of Appeal for Reclassification

The fiscal year 2005 Medicare inpatient PPS rule that created new wage index areas for the entire country clearly stated that hospitals could satisfy the proximity requirement for reclassification if they met either the CMSA standard established by the federal Office of Management and Budget (OMB) in 1990 or the CSA standard set by OMB in 2003. The purpose of having these standards is to ensure that the areas of reclassification applicants and the areas into which they seek to reclassify are sufficiently related to each other to justify their requested reclassification. The 1990 proximity standard was retained to ensure that hospitals that had long been part of the same CMSA, and part of the same wage index area, would not be unduly harmed without a means of recourse to attempt to redress that harm.

Based on their belief that they met the CMSA standards, the hospitals of Bristol County applied for county-wide reclassification into the Boston/Quincy wage index area. In denying the hospitals' application and subsequent appeal for a county-wide reclassification, the Medicare Geographic Classification Review Board stated that the hospitals did not meet the Consolidated Metropolitan Statistical Areas (CMSA) or Combined Statistical Areas (CSA) proximity criterion. We submit that when the new area definitions were adopted in 2005 that resulted in the 'splitting up' of both CMSAs and NECMAs into CBSAs, hospitals that had been part of the same CMSA retained their ability to reclassify if they met all other countywide reclassification criteria. However, hospitals in NECMAs that met the exact same criteria in New England were denied this opportunity. We believe that these hospitals do, in fact, meet the proximity standard, and had they been located anywhere else in the country, there would have been data available that would have led the review board to approve their request for reclassification.

NECMA is a concept that was developed by OMB to reflect a fundamental difference in the manner that New England states are organized politically compared to the rest of the country. In most of the country, counties are the units of political subdivisions for census purposes, and data about counties is used to determine the distribution of federal funds via the more common MSA, PMSA, and metropolitan division designations employed by the U.S. Census Bureau. In New England, however, cities and towns, not counties, are the primary units of political subdivisions. OMB created NECMAs so there would be consistent groups for nation-wide comparisons: where elsewhere in the country, MSAs were based on county units, the equivalent in New England was the NECMA. When CMS adopted the new CBSA system following the 2000 census, however, the distinction between New England NECMAs and counties elsewhere was lost. Unfortunately for the hospitals of Bristol County, NECMAs had been the major reason for their previous classification into the Boston MSA for Medicare wage index purposes – and now, the Medicare Geographic Classification Review Board had chosen not to acknowledge the NECMA classification system.

In rejecting the appeal of Bristol County's hospitals for reclassification into the Boston/Quincy wage index area based on this technicality, the Medicare Geographic Classification Review Board specifically rejected their use of data based on NECMAs – even though data based on NECMAs is uniformly used throughout the federal government on matters involving New England.

Note that, in rejecting the hospitals' appeal, the CMS Office of the Attorney Advisor suggests that the hospitals "appear to argue" their case using section 42 CFR 412.236[1] and concluded that since this section was eliminated for reclassifications for 2006, the hospitals cannot base their argument on it. The hospitals in Bristol County did not argue that this section is germane to their appeal. Rather, their argument was based on their belief that they met the CMSA standards. Absent the specific mention of 'NECMA' in 412.234, the hospitals argued that the adoption of the new area definitions split up **both** CMSAs and NECMAs into CBSAs, but the interpretation of 412.234 allowed only hospitals that had been part of the same CMSA to retain their ability to reclassify (if they met all other countywide reclassification criteria, as the Bristol County hospitals do) while depriving hospitals in NECMAs of this opportunity.

The hospitals stated that even if the *MSA standards* applied to New England, Bristol County would qualify to be combined with the Boston CMSA (using 1990 standards applied at the county, rather than the town, level). This was documented in the hospitals' appeal using a letter from the Census Bureau's chief geographer who stated clearly that *Bristol County met all the 1990 OMB criteria for inclusion in the Boston CMSA*. However, the decision ignored this assertion

We believe that the decision of the Medicare Geographic Classification Review Board and the Office of the Attorney Advisor to reject the appeal of Bristol County hospitals for reclassification was unfortunate for the hospitals – and that it does not reflect the agency's true policy intent. The hospitals of Bristol County clearly have demonstrated that they are part of the Boston area, they have long been reimbursed by Medicare as part of the Boston area, and they should continue to be viewed and treated in this manner in the future.

CMS can accomplish this by clarifying the FY 2006 Medicare inpatient PPS regulation to make it plain that NECMA data should be used when considering appeals for reclassification based on the 1990 proximity standard; by exercising its discretion to reclassify the hospitals of Bristol County into the Boston Medicare wage index area, where they rightfully belong, for FY 2006; and by removing from the proposed regulation a

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[1] **§ 412.236 Alternative criteria for hospitals located in an NECMA**
412.236(c): Criteria applicable to a group of hospitals in a NECMA. (1) All prospective payment hospitals in a NECMA must apply for redesignation. (2) The hospitals must demonstrate that the NECMA to which they are designated would be combined as part of the NECMA to which they seek redesignation if the criteria for combining NECMAs were the same as the criteria used for combining MSAs.

provision calling for the elimination of the 1990 proximity standard as a qualifying criterion for reclassification.

It is important to note that the requested regulatory clarification will not result in new, large scale efforts to reclassify; in fact, it would affect only a few hospitals in New England. It would apply only to those very limited areas in New England where CMSAs were based on cities and towns and the use of NECMAs would allow countywide designations consistent with the rest of the country. In this particular case, it would provide a reclassification opportunity for the Bristol County hospitals which were part of the 1990 Boston NECMA while restricting such an opportunity for the Rhode Island hospitals that were part of a neighboring NECMA.

Recommendation #1: Clarify in the Regulation That Qualification for Reclassification Based on the 1990 Proximity Requirement Can be Based on NECMAs

The hospitals of Bristol County ask CMS to use the final version of the FY 2006 Medicare inpatient PPS regulation to make clear to interested hospitals, as well as to the Medicare Geographic Classification Review Board, that NECMA data will be considered in applications for reclassification based on the 1990 proximity standard. Because the 1990 wage index areas for New England were based on NECMA data, we believe it is only fair and appropriate that NECMA data continue to be acceptable in demonstrating compliance with that same 1990 proximity standard for New England applicants for wage index reclassification.

Comparable circumstances anywhere else in the country would have been addressed with the use of data considered acceptable by the review board and would certainly have led to approval of the hospitals' request to reclassify. As it stands, the hospitals of Bristol County clearly meet any reasonable standard of proximity to the Boston wage index area, and except for this change of policy regarding the use of census data versus NECMA data – a change that affects only New England – they most certainly would have been reclassified into the Boston wage index area, just as hospitals in any other part of the country would have been treated under comparable circumstances.

To ensure that this problem is corrected, we recommend that in 42 CFR 412.234(a)(3)(ii), CMS should add, after "CMSA," the words "or in the case of New England, New England County Metropolitan Area, or NECMA."

Recommendation #2: Expedited Process to Reclassify the Hospitals of Bristol County Into the Boston Medicare Wage Index Area

Because it is clear that the hospitals of Bristol County would qualify for reclassification once the use of NECMA data is clarified in making such decisions, we ask the CMS administrator to use his discretion under Section 1886(d)(5)(I)(i) to make an exception to the assignment of wage index value and allow Bristol County hospitals to reclassify into the Boston wage index area for FFY 2006-2008. The Medicare Geographic Classification Review Board, responding to the 2005 regulation which was too narrowly drawn, decided to exclude NECMA data, resulting in a poor public policy decision with the potential to cause considerable harm, and we believe it is appropriate for the CMS administrator to exercise his discretion to correct this error.

Recommendation #3: Remove the Provision Calling for the Elimination of the 1990 Proximity Standard as a Criterion for Eligibility for Reclassification

The proposed FY 2006 Medicare inpatient PPS regulation calls for eliminating the 1990 proximity standard for reclassification. The 1990 standard is still needed for hospitals like those in Bristol County that clearly are part of the life of the wage index area into which they have been classified for many years. In the case of Bristol County hospitals, these hospitals clearly are part of the life of the Boston wage index area: they

compete for health care professionals with Boston and Boston-area hospitals, the residents of the communities in which they are located routinely and in significant numbers commute to Boston for work, and without the 1990 proximity standard, these hospitals will have no opportunity to reclassify back into the Boston wage index area in which they clearly belong. For these reasons, we urge CMS to retain the 1990 proximity standard for reclassification.

We appreciate your consideration of our comments and if I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (781) 272-8000, extension 173 or by email at jkirkpatrick@mhalink.org.

Sincerely,

James T. Kirkpatrick
Vice President, Health Care Finance and Managed Care Advocacy

79

THE UNIVERSITY OF NEW MEXICO • HEALTH SCIENCES CENTER
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Hefter
Hartstein
DRG/GEN. - BROOKS
FAGAN
GRUBER
KELLY
HUE

June 13, 2005

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1500-P
PO Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

I am the Director of the Cerebrovascular Disorders Program at the University of New Mexico School of Medicine and the Albuquerque VA Hospital. In 2003, I was appointed Chair of the New Mexico Stroke Task Force. I am writing to request that CMS support changes to Medicare hospital inpatient reimbursement for advanced stroke treatment in FY2006.

The impact of stroke is devastating. Stroke is the third leasing cause of death in the United States and a leading cause of long term disability. The American Heart Association estimates the cost of stroke in the United States to be over $56 billion annually. When employed by practitioners and institutions skilled in their use, acute stroke therapies such as tissue plasminogen activator can significantly reduce the disability from stroke. Even though the provision of reperfusion therapy incurs additional up-front costs, it has been shown to be cost-effective due to decreases in rehabilitation and long-term care expenses.

The undertreatement of patients presenting in the first hours of stroke, despite the availability of approved thrombolytic therapy, is a major health care problem both in New Mexico and nationwide. Data complied by the New Mexico Stroke Task Force (available on-line at http://www.health.state.nm.us/pdf/Report-Stroke_The-Challenge-09-2004.pdf) found that most hospitals lacked established protocols for reperfusion therapy and stroke care. Most health care providers had little or no experience with the use of acute stroke therapies in their patients, and had received little or no continuing medical education relevant to stroke. This is true despite predictions that the incidence of stroke in New Mexico will more than double between 2000 and 2025, and will increase at more than twice the rate of population growth. A key recommendation of the Task Force is to establish a network of primary and secondary stroke centers in the state. However, to do so, hospitals must see it in their financial interest to participate in acute stroke care despite the demands that such care places on personnel, training, and other resources.

While we do make use of reperfusion therapy when clinically indicated at the hospitals where I work, I believe that no institution in New Mexico is currently optimally equipped to treat acute stroke patients. Unfortunately, a key barrier preventing hospitals from devoting more resources to acute stroke care is

economic. Within the past 6 months, a financial impact analysis conducted by University of New Mexico Hospital showed that significant losses are currently incurred in delivering stroke care. This has greatly hindered efforts to acquire additional resources to enhance stroke care at that institution. A new DRG code for patients provided acute stroke therapy would positively alter this analysis. Increased reimbursement would encourage hospitals and health care systems to devote appropriate resources to stroke in these difficult economic times in health care.

Please support changes to stroke reimbursement for Medicare patients, who are the majority of stroke victims. I believe this could best be accomplished by creating a new DRG for acute stroke therapy. Designating a new DRG (rather than redefining of an existing DRG) appropriately recognizes the special resources and expertise of institutions providing acute reperfusion therapy, will reduce the likelihood of acute treated patients being miscoded, and will facilitate data collection on the provision of acute stroke treatments nationwide. DRG/ GEN

Thank you for your dedicated work on behalf of Medicare beneficiaries and the special attention that you have given to the needs of stroke patients. If you need additional information, please feel free to contact me by telephone at 505-265-1711 Ext. 4418 or by e-mail at graham@unm.edu.

Sincerely yours,

Glenn D Graham

Glenn D. Graham, M.D. Ph.D.
Associate Professor of Neurology, Radiology, and Neuroscience
Director, Cerebrovascular Disorders Program

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RECEIVED
JUN 21 2005
BY:----------

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Hefter
June 12, 2005
Hartstein
NT - TREITEL
WALZ

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Gentlemen and/or Mesdames:

My daughter, Dana Gambill, has had Reflex Sympathetic Dystrophy (RSD) for over four years. She has suffered greatly with excruciating pain such that she has had over 45 nerve blocks, worked with a neurobiofeedback expert to help her focus away from her pain and continues on a heavy strength Neurontin medication.

About two years ago she had a Medtronics device (neurostimulator) implanted in her rear with wires going to nerves in her spine. Such device is always on and provides a calming and cooling effect to her nerves thereby reducing pain. However, at this time she has to undergo surgery to either provide regular batteries or rechargeable batteries to her neurostimulator. Every time she or any RSD victim undergoes surgery there is a high risk that the RSD will spread. Thus Dana and others definitely want to use rechargeable batteries to prevent several surgeries required in the future to replace regular batteries NT

Dana can only work on a sporadic basis depending on how she feels and time demands of medical and physical therapy appointments. Her expenses are so heavy that she can hardly cover basic and very conservative living expenses. A rechargeable neurostimulator is essential for her very existence and that of many others afflicted with RSD. Financial help from Medicare and Medicaid is essential for Dana and others to obtain rechargeable neurostimulators. They can then be more productive and less of a cost burden to society.

Sincerely,

Robert P. Gambill

STURDY
MEMORIAL HOSPITAL

Hefter, Hartstein 8/1

HOSP REDES - KENLY
WI/Bd — ~~MILLER~~
WI/GEN/UPDATE - MILLER

June 13, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: CMS-1500-P; Medicare Program, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

To Whom it May Concern:

Sturdy Memorial Hospital believes that the Bristol County hospitals were denied an opportunity to reclassify for Medicare wage index purposes last year because of a very narrow interpretation of the FY 2005 Medicare inpatient prospective payment regulation by the Medicare Geographic Classification Review Board. We believe that our appeal for reclassification into the Boston wage index area should have been approved by the review board and request that the Centers for Medicare & Medicaid Services (CMS) revise this year's proposed FY 2006 Medicare inpatient prospective payment regulation to clarify its original intent and enable us to secure this reclassification. HOSP REDES

For this to be possible, three steps are needed: WI

1. Revise the rule to state that area wage reclassification based on the 1990 census proximity standard using CMSAs should also include New England County Metropolitan Areas (NECMA) for New England hospitals.
2. Exercise the CMS Administrator's discretion, based on the clear qualification of Bristol County hospitals to reclassify into the Boston wage index area, and reclassify us into that area at once for fiscal years 2006, 2007, and 2008.
3. Eliminate from the proposed FY 2006 rule the proposed provision that calls for eliminating the 1990 proximity standard as grounds for enabling hospitals to qualify for wage index reclassification.

Background

After almost two decades in the Boston wage index area, Sturdy Memorial Hospital, like all the Bristol County hospitals, was reassigned to the Providence wage index area in 2005. Our application for a county-wide reclassification into the Boston wage index area was denied because the Medicare Geographic Classification Review Board concluded that we failed to meet the proximity requirement; our appeal of this rejection was denied as well.

211 Park Street, P.O. Box 2963, Attleboro, Massachusetts 02703-0963 Tel. 508-222-5200 Fax 508-236-7909

We believe the review board reached an incorrect conclusion. It is clear to us that if the demographic circumstances in which we find ourselves were in evidence anywhere else in the nation except for New England, we would have been found to meet the standard established in the proximity requirement and our appeal for reclassification into the Boston wage index area would have been approved. We now seek a remedy for this situation.

The Case for Reclassification

Last year's Medicare inpatient PPS rule, which created new, nation-wide wage index areas, stated that hospitals could satisfy the proximity requirement, one of the key criteria for wage index area reclassification, if they met either the Consolidated Metropolitan Statistical Area (CMSA) standard established by the Office of Management and Budget (OMB) in 1990 or the Consolidated Statistical Area (CSA) standard established by that same office in 2003. OMB created these standards to ensure that applicants for reclassification were sufficiently related to the areas into which they sought reclassification to justify their requests for such actions. In retaining the 1990 CMSA proximity standard, CMS was taking steps to ensure that hospitals that had long been part of a CMSA, and therefore of a wage index area, had a reasonable means of appeal if the nation-wide reclassification of hospitals left them in a new wage index area that they thought was disadvantageous and inappropriate.

This is the situation that Sturdy and the hospitals of Bristol County found ourselves in last year: in a new wage index area – the Providence area – that we felt would cause considerable harm to our financial health. Believing that we met the CMS criteria for reclassification into the Boston wage index area, we worked together and filed for a county-wide reclassification, citing the 1990 CMSA standard as proof that we met the proximity requirement. The Medicare Geographic Classification Review Board, however, rejected our application and subsequent appeal, ruling that we met neither the 1990 CMSA standard nor the 2003 CSA standard for proximity.

We believe that these decisions reflect an inadequate understanding of both the concept of proximity and the unique qualities of the manner in which New England local governments are organized and that, had the same demographic conditions existed anywhere else in the country, our application for reclassification would have been approved.

At the heart of the review board's rejection of our county-wide application and appeal was its specific rejection of our use of data based on New England County Metropolitan Areas, or NECMA, rather than CMSA or CSA data, in our appeal. The NECMA designation was created by OMB and adopted by CMS to reflect a fundamental difference in the manner in which New England political subdivisions are organized: whereas in most of the country the primary unit of political subdivision for census and other purposes is the county, in New England the primary units of political subdivision are cities and towns. CMS used NECMAs to create a level playing field: to have consistent groupings for nation-wide comparisons. When CMS adopted the Core-Based Statistical Area (CBSA) system following the 2003 census, however, the review board apparently concluded that it no longer needed to accept NECMA data – a surprising conclusion in light of the regulation's preservation of the 1990 proximity requirement as a criterion for qualifying for reclassification. For New England hospitals, NECMA data would have to be the primary means through which to demonstrate compliance with the 1990 proximity requirement, and now, that avenue had been closed off to us. In other parts of the country, hospitals that had been part of the same CMSA still could reclassify if they met all of the other reclassification criteria. Only hospitals in New England, based on the narrow interpretation of the Medicare Geographic Classification Review Board, had been singled out and denied an equivalent opportunity in this manner. (In fact, had NECMAs not been

used, according to the chief geographer of the U.S. Census Bureau, Bristol County almost certainly would have been designated a part of the Boston CMSA. A copy of his letter attesting to this is attached.) We believe this is wrong and unfair and led to a bad public policy decision – a decision that we now ask CMS to remedy.

We believe it is entirely appropriate for reclassification applicants to use NECMA data to demonstrate compliance with a proximity requirement that uses NECMA data as its foundation. Below, we will address how to ensure that this can be done in the future. We also wish to note that addressing this problem would amount to a relatively minor refinement, not a large-scale, nation-wide reclassification movement. The conditions that affect us can be found only in New England – predominantly in Massachusetts and possibly in a few parts of New Hampshire; Rhode Island hospitals, for example, would not be able to reclassify into the Boston wage index area.

The Cost of Our Inability to Reclassify

Sturdy Memorial Hospital, long a part of the Boston wage index area, will pay a high price for our classification into the Providence wage index area if this situation is not rectified: we will lose several hundred thousand dollars in annual Medicare revenue.

The purpose of the Medicare wage index system is to help Medicare reimburse hospitals based on the varying cost of living, and employing workers, throughout the country. Simply put, workers with comparable skills are paid different amounts of money in different parts of the country, and the wage index system helps ensure that hospitals are neither overpaid nor underpaid but are fairly paid for the services of these workers.

Of the 250,000 working adults who reside in Bristol County, nearly a quarter – 22.1 percent – travel to work in Boston. By comparison, only a little more than one-third of that figure – 8.5 percent – travel to Providence for work. Among Bristol County residents who work in hospitals, however, even more – 27 percent, according to the Census Bureau's Bureau of Economic Analysis – commute to other Massachusetts counties, primarily in the Boston area, for work. Clearly, this demonstrates that the hospitals in Bristol County are very much more a part of the economic life of the Boston area and that we meet any reasonable standard of proximity to the Boston wage index area.

Recommended Regulatory Changes

We urge CMS to correct this injustice in the final version of the FY 2006 Medicare inpatient rule. This can be done through three specific steps.

Step One: Revise the Regulation to Make Clear that NECMA Data Can Be Considered in Reclassification Applications Based on the 1990 Proximity Requirement

Sturdy Memorial Hospital asks CMS to revise the regulation to clarify to hospitals that they can use NECMA data to support applications for reclassification based on the 1990 proximity standard and to direct the Medicare Geographic Classification Review Board that it must consider NECMA data when evaluating applications for reclassification based on that 1990 proximity requirement. To effect this change, we recommend that CMS add, after "CMSA" in 42 CFR 412.234(a)(3)(ii), the phrase "or in the case of New England, New England County Metropolitan Area, or NECMA."

Step Two: Exercise the Administrator's Discretion to Reclassify Us Immediately

Section 1886(d)(5)(l)(i) authorizes the CMS Administrator to make unilateral exceptions to wage index classifications, and we request that the CMS Administrator do exactly that and reclassify our hospital into the Boston wage index areas right away for fiscal years 2006, 2007, and 2008. Because the Medicare Geographic Classification Review Board ruled too narrowly on our appeal and its decision could cause serious harm to us, we believe this is an appropriate use of the Administrator's discretion.

Step Three: Preserve Use of the 1990 Proximity Requirement Standard as a Criterion for Reclassification Eligibility

The proposed regulation includes a provision that would eliminate the 1990 proximity standard as a criterion for reclassification. Because situations like ours will arise, and because the 1990 standard is the only reasonable means through which hospitals like ours can demonstrate that we truly are part of the community into which we seek reclassification, we strongly urge CMS to preserve this criterion and not to remove it from the regulation. We have been an integral part of this community for decades, and we should continue to remain so.

Bristol County Hospitals Meet the Other Criteria for Reclassification

To qualify for reclassification, applicant hospitals must fulfill three criteria: they must be in a county contiguous to the CMSA into which they seek reclassification; they must meet the proximity requirement; and they must meet the wage requirement. We believes we meet all three of these requirements:

1. Bristol County, in which we are located is immediately adjacent to the Boston CMSA and wage index area.
2. As this letter demonstrates, we believe we meet the proximity requirement.
3. All hospitals based in Bristol County, as defined by CMS, as well as all hospitals with operations in the county, meet the wage requirement. The Medicare Geographic Classification Review Board confirmed the former in its review of our county-wide application last year, and documentation of this compliance accompanies this letter.

Conclusion

We recognize the considerable challenge CMS faced in crafting new wage index areas for the entire country based on the results of the 2000 census. This was an enormous undertaking, and CMS has appropriately given hospitals opportunities to appeal its classification decisions. We believe that the decision of the Medicare Geographic Classification Review Board to reject the group appeal of the Bristol County hospitals for reclassification was an unfortunate one – and that it should be corrected. We clearly have demonstrated that we are part of the Boston area, we have long been reimbursed by Medicare as part of the Boston area, and we should continue to be viewed and treated in this manner in the future.

CMS can accomplish this by revising the FY 2006 Medicare inpatient PPS regulation to make clear that NECMA data can be considered in reclassification applications based on the 1990 proximity requirement; by exercising the CMS Administrator's discretion to reclassify us immediately; and by preserving the use of the 1990 proximity requirement as a criterion for reclassification eligibility.

We appreciate your consideration of our comments and welcome any questions you may have about them.

Sincerely,

Linda Shyavitz
President & CEO

Enclosures

CAH/REL - COLLINS Hefter
MOREY Hartstein
SMITH
82

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
PO Box 8011
Baltimore, MD 21244-1850

RE: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

To Whom It May Concern:

Thank you for the opportunity to express my concerns about the proposed changes to the Hospital Inpatient Prospective Payment Systems, specifically as it concerns Critical Access Hospitals.

I have read through the proposed regulatory change and am confused and dismayed about the drastic reversal of direction the regulations anticipate. I am aware of a small rural hospital, LaGrange Community Hospital, in northeast Indiana that was recently granted a Critical Access Hospital designation under the necessary provider designation. That hospital was sold to an area not-for-profit hospital group because it was unable to generate the funds necessary to upgrade its medical technology to keep pace with the expected standard of care in Indiana. Nor, was the hospital able to make necessary improvements to its physical plant so that annual maintenance costs could be reduced.

CAH/Reloc

This Critical Access Hospital is in a small, rural community that serves a unique population of Amish and English residents. Access to the current hospital is not optimal, given the special needs of the Amish in the area. The not-for-profit hospital group purchased the hospital, and the County Leaders approved the sale with the understanding that a new hospital would be built to better serve this community. If the conditions of the proposed regulation were to be imposed, the advent of a new facility, better located to serve the community, would be jeopardized.

According to the regulation, Critical Access Hospitals can remain so designated if they don't rebuild; rebuild within 250 yards of the current site, and/or had plans to do so prior to December 8, 2003. The designation of the hospital as Critical Access, necessary provider was granted in February 2005. The hospital sold in May 2005. A new Critical Access Hospital facility, in a more appropriate location for the 37,000 LaGrange, Indiana citizens may have to be delayed, or worse, abandoned.

I would strongly urge you to consider the long-term ramifications of making this regulatory adjustment for this and other similarly situated small community, rural hospitals across the country. Small, rural communities deserve quality healthcare provided locally, too.

Thank you.

Respectfully,

John M. Hatcher

Copy To: U.S. Senator Richard Lugar
U.S. Senator Evan Bayh
U.S. Representative Mark Souder

83

RECEIVED
JUN 21 2005
BY:.....

RHEA MEDICAL CENTER

HOSPITAL NURSING HOME PROFESSIONAL BUILDING

June 13, 2005

Hefter
Hartstein
CAH/RELOC - Collins
Morey
Smith

IMPACT - KRAEMER ~~- ANALYST~~

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Critical Access Hospitals

To Whom It May Concern:

Under the Medicare Prescription Drug Improvement and Modernization Act (MMA), enacted 12/8/03, as of 1/1/06, new necessary provider Critical Access Hospitals (CAH's) will no longer be granted and all future CAH's must meet federal eligibility tests (including mileage). While the MMA permitted necessary providers to retain their CAH status, it appeared to only deal directly with those remaining at their present location. As such, the healthcare industry in general, lacked a consensus in its interpretation of the MMA and its impact on necessary providers planning to relocate after 1/1/06. A common belief was regional CMS offices had the authority to approve the relocation of necessary providers after 1/1/06 on a case-by-case basis. CAH/RELOC

The new CMS proposal seeks to clarify the issue of relocations and offers the stark reality that only a few CAH's will be grandfathered prior to the cut-off date of 1/1/06, with no other exceptions. To maintain their CAH status, all necessary providers must submit an application to CMS for relocation prior to 1/1/06 and be able to: (1) demonstrate at the new location they will continue to meet the necessary provider criteria that was used to originally receive a State waiver, serve at least 75% of the same service area, offer 75% of the same services, utilize 75% of the same staff, maintain compliance with all conditions of participation (42 CFR 485), and (2) demonstrate that construction plans were under development prior to the enactment of the MMA. CAH's moving within 250 yards of their current building, or to contiguous land that was owned prior to 12/3/03 will be exempted from the relocation rules.

Our concern is that the CMS Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule (FY 2006) prohibits any CAH operating with a Necessary Provider Designation from relocating its hospital and maintaining its CAH status unless the move is completed by 1/1/06, or grandfathered. The only exception that currently exists is for necessary provider CAH's which had construction plans already under development as of 12/8/03 and can demonstrate this in their application for relocation to be submitted to CMS prior to 1/1/06.

7900 RHEA COUNTY HIGHWAY DAYTON, TENNESSEE 37321
PHONE (423) 775-1121 FAX (423) 775-6621

With the exception of a select group of CAH's which may receive grandfather status under the relocation sunset provision, this proposal makes it virtually impossible for any CAH operating, including Rhea Medical Center with a Necessary Provider Designation to ever afford an off-site replacement facility project, as it would immediately become ineligible for cost-based reimbursement. It would seem that if the CAH remained within its primary market area a replacement facility project should be encouraged.

If the Proposal is approved as-is, the impact would derail the modernization of a major percentage of America's antiquated CAH's that face limited on-site renovation or replacement options. If enacted, Rhea Medical Center will be faced with the choice of either undertaking often more costly, space-constrained, operationally inefficient on-site construction projects, or relinquish their cost-based reimbursement, the "financial life preserver" necessary to offer quality healthcare to their communities. This would put rural hospitals at a major disadvantage in competing with larger more financially secure hospitals in attracting physicians and patients in order to preserve market share and remain operationally viable.

IMPACT

In the situation of Rhea Medical Center, we applied for CAH status as a Necessary Provider in order to receive the reimbursement of capital cost allowed under the CAH program so that we could build a badly needed replacement facility. This was to be built on a parcel of land large enough to provide for the Rhea County community's needs many years into the future. The land expected to be chosen is 1.3 miles away. We have been in search of a parcel since the late 1990's but progress was slowed by the crushing blow dealt us be the Balanced Budget Amendment (BBA). The search was resumed in earnest in 2003 after the BBA's fix came to bear. A project team was hired in August of 2004 to provide professional assistance to the search. Plans were beginning to be drawn in April, 2005 while engineering due diligence on the parcel continued. The Certificate of Need was filed with the State of Tennessee in early May.

We are desperately in need of an improved campus designed with room to grow. Since the original hospital was built, the population of our county has nearly doubled in size. To meet the needs of this growth, Rhea Medical Center, Rhea County's only hospital, needs to replace its original 1957 facility. Applying for and receiving participation in CAH program was intended to help us reach our goal.

If the CAH program is now changed as proposed this will serve to thwart our plans similar to how the BBA did this in the past. It serves no useful purpose to pull the rug from under rural CAH facilities such as ours as is now proposed.

Sincerely,

Kennedy Croom, Jr.
Chief Executive Officer

JUN 17 2005

84

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Jackson, MS
Tupelo, MS
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Tampa, FL

RECEIVED
JUN 21 2005
BY:

Hefter
Hartstein
KENLY
Miller

HOSP REDES -

June 16, 2005

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VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Hospital Reclassifications – CMS-1500-P
– Iuka Hospital
– Medicare Provider No. 25-0002

Dear Sir or Madam:

In its proposed rule entitled, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates," published in the May 4, 2005 Federal Register, the Centers for Medicare and Medicaid Services ("CMS") solicited public comments under various proposals that would affect the wage index reclassification process for various hospitals. *See* 70 Fed. Reg. 23,306 (May 4, 2005). This comment is submitted on behalf of Iuka Hospital, CMS Provider No. 25-0002. The purpose of this comment is to request guidance from CMS concerning reclassification of hospitals under Section 508 of the Medicare Modernization Act of 2003.

1. Reclassification Under Section 508 of the Medicare Modernization Act of 2003. GeoReclass

Pursuant to Section 508 of Public Law 108-173 (the "Medicare Modernization Act of 2003" or "MMA"), qualifying hospitals were allowed to appeal the wage index classification otherwise applicable to the hospitals and apply for reclassification to other areas in the states in which the hospitals were located. The process for reclassification was implemented through notices published in the Federal Register on January 6, 2004 and February 13, 2004. Pursuant to this process, Iuka Hospital applied for and received wage index reclassification from the rural Mississippi area to the Gulfport-Biloxi, Mississippi CBSA. Reclassification pursuant to Section 508 of the MMA is applicable to discharges occurring between April 1, 2004 and March 31, 2007.

HOSP REDES

VICTORY
MEMORIAL
HOSPITAL

699 92nd Street
Brooklyn, New York 11228-3625
(718) 567-1234

85

Labor Rel. Share

June 15, 2005

Hefter
Hartstein
M. Knight
Seifert
V. Miller

Centers for Medicare & Medicaid Services U.S.
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Subject: Labor-Related Share

To Whom it May Concern:

I am writing on behalf of Victory Memorial Hospital to express our opposition to the changes that the Centers for Medicare & Medicaid Services (CMS) has proposed in the FY 2006 Medicare inpatient PPS regulation governing the labor-related share of Medicare payments to hospitals. The proposed regulation calls for reducing the labor-related share from 71.1 percent to 69.7 percent for hospitals located in areas with a wage index greater than 1.0 and would cost our hospital approximately $83,000 in lost Medicare revenue.

Three years ago, CMS proposed increasing the labor-related share for all hospitals from 71.1 percent to 72.5 percent. The agency, however, expressed concern over the harmful impact this would have on rural hospitals and withdrew the proposal in favor of further analysis of the methodology it used to compute this proposal. While CMS was performing this analysis, Congress passed legislation that set the labor-related share at 62 percent for hospitals with a wage index of 1.0 or less to increase payments to most rural hospitals.

In proposing to reduce the labor-related share for FY 2006 for hospitals with a wage index greater than 1.0 - primarily urban hospitals - CMS now is using the same methodology it rejected three years ago. We do not understand why a methodology rejected three years ago is now considered valid. If that methodology is now, in fact, considered valid, CMS's decision not to raise the wage index as originally proposed three years ago resulted in urban hospitals being underpaid by Medicare since that time.

Since this change will decrease Medicare revenue for all affected hospitals - those whose wage index is greater than 1.0 - CMS proposes achieving budget neutrality by redistributing this money by increasing the standardized amount for all hospitals. This approach will result in a financial windfall for *all* hospitals with a wage index of 1.0 or less - that is, for most rural hospitals. If CMS believes that 69.7 percent is the true, appropriate figure for labor-related share and hospitals with a wage index less than 1.0 are already, in effect, getting more generous payments than they should, we question the decision to give these hospitals - that is, most rural hospitals - even more than they already receive.

This proposal also raises concerns about what we view as another attempt by the federal government to penalize urban hospitals for the benefit of rural hospitals. In recent years, a number of new policies have been adopted or rejected, both by Congress and the administration, based primarily on their damaging impact on rural hospitals. They include CMS's decision of three years ago not to raise the

labor-related share because that action would hurt rural hospitals (and ignoring the benefits it offered to urban hospitals); the enormous supplemental benefits directed to rural hospitals by Congress through the Medicare Modernization Act of 2003 while that legislation virtually ignored the far greater needs of urban hospitals; the FY 2005 regulatory change that steered residency slots to rural hospitals and away from urban hospitals; and CMS's failure in recent years to meet its statutory target for outlier payments - a practice that disproportionately disadvantages urban hospitals.

These and other actions have been undertaken despite clear evidence that urban hospitals are in far worse financial condition than rural hospitals. The cumulative effects of years of caring for uninsured, under-insured, and Medicaid patients are taking their toll on urban hospitals: more and more of us are losing money. In an industry in which a positive operating margin of four percent is considered necessary to operate effectively, a 2003 study by the National Association of Urban Hospitals found that among hospitals that qualify for Medicare DSH payments, the collective financial performance of urban hospitals nation-wide is 25 times worse than that of rural hospitals. Collectively, the operating margins of urban Medicare DSH hospitals in the U.S. is *minus* 5.7 percent - a figure that suggests that without intervention, many of those urban safety-net hospitals may soon be forced to close their doors. That same study found that large urban hospitals that provide at least 15 percent of their services to Medicaid patients have an average operating margin of *negative* 8.52 percent. At the same time, there have been no credible studies that suggest that rural hospitals are being underpaid by Medicare. Most, in fact, conclude that rural hospitals are adequately reimbursed for the services they provide to Medicare beneficiaries.

For these reasons, we urge CMS not to reduce the labor-related share of the Medicare wage index.

Sincerely,

Krishin Bhatia
Administrator & COO

8.6

TEXAS HOSPITAL ASSOCIATION

June 13, 2005

Helfer
Hartstein

CAH/RELOC - Collins
Morey
Smith

Centers for Medicare & Medicaid Services
Attention: CMS-1500-P
P. O. Box 8011
Baltimore, MD 21244-1850

Re. Proposed Regulations for Critical Access Hospital Renovation, Relocation

To Whom It May Concern:

I am mailing Texas Hospital Association's comments regarding the above referenced documents because I was uncertain whether or not the entire e-mailed document reached your office.

Please call me if you have any questions about these comments.

Sincerely yours,

Richard Hoeth

Richard Hoeth, FACHE, CAE
Vice President, Rural Health
and Member Relations

Enclosure

Serving Hospitals and Health Systems
6225 U.S. Highway 290 East • Post Office Box 15587, Austin, Texas 78761-5587 • 512/465-1000 • Fax: 512/465-1090

Texas Hospital Association Comments re. CMS-1500-P, Proposed Regulations regarding Critical Access Hospitals:

CAH/RELOC – COLLINS MOREY SMITH

Determination of the Relocation Status of a CAH

Section B. 3 a. (1). Replacement in the same location

CMS has proposed that if a CAH is constructing renovation of the same building in the same location, the renovation is considered to be a replacement of the same provider and not relocation. CMS goes on to say that the construction would be considered a replacement "if construction was undertaken within 250 yards of the current building, then CMS would consider that construction to be a replacement and the provisions of the grandfathered necessary provider designation would continue to apply regardless of when the construction or renovation work commenced and was completed."

THA's Comment: The 250 yard measurement is an arbitrary number, which does not take into consideration the actual physical location of a hospital and its proposed renovation. For example, Pecos County General Hospital in Iraan, Texas plans to replace its outmoded hospital facilities on a plot of land donated to the hospital and located within 250 to 300 yards from its current physical site (see attachment). The entire town of Iraan is only about 6 to 8 blocks long. It does not make any sense for CMS to deny a grandfather status to that facility and its community based upon a few yards, established on an arbitrary basis. Iraan is one of two hospitals serving Pecos county, the other hospital being in Fort Stockton, over 50 miles away.

Section B 3 a. (2) Relocation of a CAH

CAH

CMS has proposed that "if the CAH is constructing a new facility in a location that does not qualify the construction as replacement of an existing facility in the same location under the criteria in the preceding paragraph, CMS would need to determine if this building would be a relocation of the current provider or a cessation of business at one location and establishment of business at another location". CMS goes on to say that "in the event CMS determines the rebuilding of the CAH in a different location is a relocation, the provider agreement would continue to apply to the CAH at the new location. In addition to the relocation being within the same service area, serving the same population, the CAH would need to be providing essentially the same services with the same staff; that is, at least 75% of the range of services are maintained in the new location as the same provider of services. The logic used is that the 75% threshold is the same threshold used in other provider designation policies, such as the provider-based policies at 413.65(e)(3)(ii).

THA's Comment: Again, the 75% rule is an arbitrary number, and not based upon any community assessment of patient need or the actual basis for relocation. In addition, a restriction of new development of services (or elimination of certain services no longer needed, for that matter) is discriminatory to Critical Access Hospitals. No PPS hospitals are restricted from adding or deleting new services, nor should they be. Critical Access Hospitals should not be treated any differently.

For example, Bayside Community Hospital in Anahuac has proposed building a new hospital a few miles north of their present location because their community served has migrated toward that area, which is adjacent to Interstate 10. The new location addresses certain access and emergency care issues, since the current hospital is located more inland and near a high water area. In addition, the hospital needs to conform to new bio-terrorism standards, more easily met in the new location.

If Bayside (or other Critical Access Hospitals decide to build a replacement hospital within their primary identified service area and continue to serve their patients' needs in accordance with a current community needs assessment, then there is no reason that CMS should not consider their project valid under their current provider agreements.

Section B 3 a (3) Cessation of business at one location

THA's Comment: Only Critical Access Hospitals which are relocating their hospitals to a physical location well outside of their currently defined primary service area, based upon an analysis of their current patient demographic data, should be classified as "ceasing business at one location". All other CAHs should be allowed to renovate/replace their facilities without the threat of losing their CAH designation.

Section B 3 b (1)

CMS proposes using specified relocation criteria as the initial step in determining necessary provider status. THA has already commented regarding one of those criteria, the 75% rule for the same service area. However, this section also requires 75% of the same staff, including medical staff, contracted staff, and employees. In addition, another proposed criteria would require "a demonstration that construction plans were 'under development' prior to the effective date of Pub. L. 108-173 (December 8, 2003) in the application the CAH submits to continue using a necessary provider designation."

THA's Comment: Regarding the 75% rule being applied to medical staff, contracted staff, and employees, again this is a very artificial rule, and not based upon any hospital's actual staffing needs. Some rural hospitals may not have no more than three (3) active staff physicians. If one of the three does not decide to practice at the new hospital, then it makes no sense to deny the hospital necessary provider status, if only 67% (two out of three) doctors decide to practice at the new hospital. It would be more practical and reasonable when the new hospital opens for CMS to review staffing patterns at that time and to determine whether or not there are any substantial differences, and whether or not those differences are based upon programs, services, and the adequate and appropriate staffing needed to deliver those services, rather than a general percent.

With respect to a Critical Access Hospital needing to have its construction plans "under development" on or before December 8, 2003, it is totally unreasonable for any organization to comply with a new regulation retrospectively. In addition, this regulation is contrary to the Congressional intent of Congress that Critical Access Hospitals should be prevented from replacing or relocating their hospital facilities, many of which were originally constructed from Hill Burton funds over 50 years ago. This language should be stricken in its entirety from the regulations.

Additional Comments:

1. The proposed aforementioned regulations are contrary to the original intent of the Balanced Budget Act of 1997, which contained the authority for states to establish Critical Access Hospital programs for low volume rural hospitals. The intent of the legislation was to level the playing field for small, rural hospitals, which were historically inadequately reimbursed by Medicare in comparison to the larger PPS hospitals. There is no language in the Medicare Modernization Act which would lead any one to believe that Congress has altered its original intent, and so these proposed regulations are punitive toward Critical Access Hospitals.

2. The proposed regulations are discriminatory toward Critical Access Hospitals and deny them and their rural residents an equal opportunity to have access to the same level and quality of care, new technology, and capital improvements available to other (PPS) facilities. This shows a lack of understanding by CMS of the importance of protecting CAH facilities, which are our "safety net hospitals".

3. If changes in population centers have resulted in the reclassification of rural hospitals to urban and vice versa, then the same logic should apply to hospital renovation and relocation projects. Neither the 250 yard nor the 75% rule are reasonable or logical. The location of a renovated or replacement hospital should be based upon the present day service area and patient needs of a CAH. A hospital should not lose its CAH status, unless a study of its current community assessment, market area, and staffing following relocation to the new hospital result in the finding that the organization is attempting to engage in blatant abuse of the Medicare conditions of compliance.

4. According to MEDPAC figures, it requires approximately $3 billion dollars annually for CMS to operate the Critical Access Hospital program vs. the $239 billion dollars for all hospital expenses. This is slightly more than 1% of the total annual CMS hospital budget, but it concerns the most fragile and needed hospital providers in the nation. If anything, CMS should be writing regulations to protect, rather than to discriminate against or punish this group of hospitals. The irony is that CMS would pay much more for care at other PPS facilities if they adopt regulations such as the ones proposed.

Finally, THA recommends elimination of the 250 yard requirement for renovation projects, as well as the 75% requirement for residents served and hospital staff, including medical staff. Critical Access Hospitals designated by their states as necessary providers should be grandfathered for both renovation and relocation projects based upon their current assessment of community needs and the current demographics of their patient service areas. Government regulations should not take precedence over a community's determination of facilities and staffing necessary to meet current, defined local health care needs.

Sincerely Yours,

Richard Hoeth

Richard Hoeth, FACHE, CAE
Vice President, Rural Health
and Member Relations

June 13, 2005

87

June 14, 2005

Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

CAH/RELOC – Hefter Hartstein Collins, Morey, Smith

To Whom It May Concern:

As the Administrator for Bladen County Hospital in rural eastern North Carolina, I am writing to tell our story about how the proposed rules to modify the necessary provider status for Critical Access hospitals might limit our options to replace our 53 year old building.

The proposed rules were published in the Federal Register on May 4, 2005 and comments are due no later than June 24, 2005. Please consider this correspondence as our written comments in this regard.

Bladen County Hospital operates as an enterprise unit of the county and serves all people of our county, as a primary care site. Through Bladen Medical Associates, we operate four rural health sites throughout the county and we are the only hospital provider within the county and within a 25 mile radius. We were experiencing paralyzing losses after the implementation of the Balanced Budget Act in 1998, but through the Balanced Budget Reconciliation Act, we were able to find relief through the Critical Access Designation that we received in October, 2003.

Our Critical Access Hospital (CAH) currently provides inpatient services, labor and delivery services and critical care services for patients under observation. We've recently recruited two Obstetrician and Gynecologists to our area to preserve the access to delivery services within the county. We have also recruited two general surgeons to build access to general surgery within a reasonable distance for most of

our population. The drive to the next closest hospital is more than 30 minutes. Our emergency services are the only urgent or emergent services available in the service area, as well. Increasingly we are transferring critical patients from our primary facility to medical centers in Wilmington, Lumberton and surrounding areas. It is not unusual to be told that our emergency service saved the life of the patient ultimately transferred to a larger medical center.

Our concern is that we are operating in a building that is aging and in desperate need of repair. The hospital was designed as an inpatient hospital; however, eighty percent of our business is outpatient in nature. Fitting outpatient services in an inpatient building is inefficient and ineffective. We have only two operating rooms, one of which has to be reserved for emergency surgery, such as, cesarean sections. A replacement hospital will enhance our efficiencies in outpatient service and reduce utility costs. Our roof, alone, will require more than $1 Million dollars of repair. We are landlocked by current development at our current site, and there is no land for development of expanded or replacement facilities. We are conducting a feasibility to relocate the hospital to the Elizabethtown NC Hwy 87 Bypass, improving accessibility of our hospital to the local community. Our survival is dependent on the discretionary referral of our insured community. The image projected by a new hospital will be instrumental in promoting our ability to operate a fiscally sound hospital, for the future. Our Critical Access designation has helped our ability to reinvest in our medical services and build capital replacement for equipment, as well as, facility.

Losing our Critical Access designation, would jeopardize the feasibility of building a new hospital. History has shown that we can not survive financially without the Critical Access funding. The ruling, as proposed, would force us to continue to pass-through high costs for reimbursement that is not otherwise subsidized by a private referral base, and would prohibit us from building efficiencies and reducing fixed cost in an obsolete facility. Our request is that the hospitals that are currently qualified under the "necessary provider" provision for Critical Access have the ability to relocate their services to a replacement facility without losing their designation as a critical access provider.

We can demonstrate that we meet the following provisions as proposed:

- Documentation that the CAH will meet the same necessary provider criteria that were established when the waiver was originally issued,
- Assurance that following relocation, the CAH will be servicing the same community and offering the same services by showing it is:
    - Serving at lease 75% of the same service area,
    - Offering at least 75% of the same services, and
    - Staffed by at least 75% of the same staff including medical staff, contracted staff and employees
- Assurance that the CAH will remain in compliance with the Conditions of Participation in the new location.
- Building and relocating our facility does not position Bladen County Hospital as any less necessary or critical to the access to medical facilities in a rural environment.

We would not meet the limitations of the deadlines as proposed, due to the timing of our determination and the publication in the Federal Register in May 2005. However, with consideration of elimination of the deadlines or extension of those deadlines, we would be able to meet the following conditions:

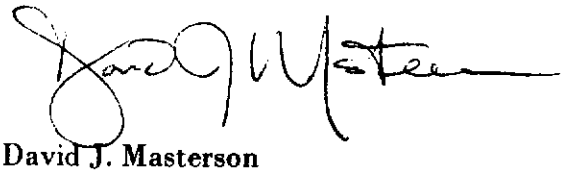
- The CAH must have submitted a request for a new facility to the State agency by a reasonable, future deadline, and
- Demonstrate that the construction plans were "under development" at a reasonable, future date.

Bladen County hospital would function as essentially the same provider by relocating all services to the new site and would cease operation in the original location.

In the proposal to revise SS 485.610 of the regulations, please reconsider the arbitrary deadlines, providing current CAH's time to plan for a replacement facility, submit proposals for state approval and prepare for changes in the regulation that were not published until recently. CMS notes that it is the CAH's right to construct a new facility and remove itself from CAH certification as the result of new construction. Unfortunately, our right is not really a choice given the proposal as recommended.

I would be happy to provide further evidence or testimony to this dilemma, and I thank you for considering my comments on behalf of the citizens of Bladen County.

Respectfully submitted,



David J. Masterson
Administrator
Bladen County Hospital

MCE
NT
DRG

Date: 06/13/2005

Hefler
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue
Wal 2
Treitel

Submitter : Mr. James Gezelman

Organization : P.N. U.S.A.

Category : Individual

Issue Areas/Comments

Issues

Medicare Code Editor

Being on Medicare has not been easy and I thank my country for what it has done for me. However there is a lot of room for improvement and I know I am having a hard time just getting a anodyne light machine. I have been tested on it and it looks like it would be a great thing for me. I do not think it will kill all of my pain , but I do think it will deaden some of it expecially when combined with the Rebuilder that I never got reimbursed for by Medicare. Then I hope to lower my pain meds.If all else fails I sure think I should have the option of deciding if I would like to try the Medtronic pain pump or the electrical stimulator on the spine. I wish there was a way that the people making these decisions could experience some of the driffrent types of pain for a few minunts so they could learn first hand how important this is. Sorry about my spelling ,James Gezelman

Issues

I have been in pain for a good part of my 48 years. The broken bones pain and the P.N. together are enough to make one consitter taking ones oun life. To tell you the truth If I had not cleaned up two suicides by gun shot and seen the affect and felt it as I was a close friend of one of them, I would be dead now. It is only the fact that I have living relatives that I have not done it. I have tryed several outside the body electronic devices and they have helped. I am doing every thing in my power to stop the pain and get well enough to become a usefull productive person and get of SSI and Medicare. I am trying to aquire one more electronic machine , the anodyne light machine that has helped in PT. That with the Rebuilder and tens I think will help me a lot. However if more is needed I would like to think that the Medtronic's implant machines, the pump or the electrical signal system will be there as a backup for me rather then a bullet.Most off the people who make the decisions wheather we the now poor because of pain have no idea of how bad pain can really get. I am sure that some who sit on these prestigious boards might say I once broke this or that doing sports in college. Or maybe threr are a few who were more severe. But the majority have never expericenced prolonged cronic pain. So how can they see or feel what it is like before they vote on where monies should go? Perhaps they should go to some of the pain clinices around the country and ask the patiants how it feels. I am sure that talking to people like myself face to face might give them better insight into what true aganey can really feal like. I am sorry that my spelling is not better but i belive you get the jest of what I am trying to say and I hope you put the vote marks where they should go. James Gezelman

SIERRA VISTA HOSPITAL

89

RECEIVED
JUN 21 2005
BY:.....

Hefter
Hartstein
CAH/Reloc - Collins
Morey
Smith

May 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1500-P
Room 445-G, Hubert Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

05 JUN 14 PM 3:19

RE: Oppose Medicare's Proposed Construction Ban on Critical Access Hospitals

To Whom It May Concern:

After years of struggle Sierra Vista Hospital in Truth or Consequences, Sierra County, New Mexico now sees the possibility, the very real necessity of replacing a fifty-year old facility with an updated, more proficient and cost-effective facility to serve the needs of the citizens of our State. As a member of the Governing Board of that facility I would ask that the arbitrary deadline on Critical Access Hospital replacement or relocation in the Inpatient Prospective Payment System be ***deleted.*** CAH/Reloc

Sierra Vista Hospital is a Sole Provider, Critical Access Hospital located in Sierra County New Mexico ***seventy miles from the nearest facility***. It is located on I-25; a major heavily used Interstate Highway. Elephant Butte and Caballo Lakes make this a tourist and recreation area with State Parks that draw well over 100,000 visitors annually, as many as 100,000 on a holiday weekend, making Sierra Vista Hospital the only facility within 70 miles that is available to these visitors and citizens in a critical emergency, to stabilize, treat and if need be transfer to a tertiary facility 70 to 150 miles away. When the Critical Access Program came into being this was precisely what it was intended for.

The date restriction (construction plans that began before December 8, 2003) puts Sierra Vista Hospital at risk to lose its CAH designation if plans proceed to update or construct a new facility.

It was clearly not the intent of Congress in the Medicare Modernization Act that a Critical Access Hospital designated as a Sole Provider, be perpetually prohibited from replacing or relocating their facility. This is especially true of those that are, as Sierra Vista Hospital, fifty years old. Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare more over time. The higher costs of operating in an outdated, retrofitted building far exceed the slightly higher cost of rebuilding. In the case of Sierra Vista Hospital, a facility built in the early fifties, the cost of maintenance alone is staggering let alone the cost of meeting current safety codes in an aged building. We are

800 East Ninth Avenue Truth or Consequences, NM 87901 Phone: (505) 894-2111 Fax: (505) 894-7659

currently operating on a Waiver from the Life Safety Code Program of the New Mexico Health Facility Licensing and Certification Bureau for five years due to Life Safety Code violations. Upgrading this facility to Code is impossible.

A ban on major construction projects developed after 12/03/03, is clearly an over-reaction to the rule that would require assurance that after construction the Critical Access Hospital (SVH) will be serving the same community, operating essentially the same services with essentially the same staff. There is no basis in law for the assertion that relocation of a Critical Access Hospital with Sole Provider Status within a community constitutes a cessation of business and loss of its Provider Number and Agreement.

A Critical Access Hospital with Sole Provider designation is associated with its current Medicare Provider Agreement, which should remain intact unless there is a fundamental change in business. It is a long-standing policy that the provider agreement describes the legal entity (SVH) and services provided, ***not the physical structure or location.***

This might even suggest that CMS investigate once again the original intent of the CAH Program, what it was originally intended to achieve before, as is often the case, there were those that took advantage of the programs intent. If a critical access facility is abiding by the standards set forth, there should be no reason for them to lose the important local control especially regarding the construction and upkeep plans for the facility.

Sierra Vista Hospital in Truth or Consequences, New Mexico ***respectfully calls for the deletion of the arbitrary deadline on Critical Access Hospital replacement/relocation in the Inpatient Prospective Payment System Final Rule.***

Yours very truly,

Albert Dunkin, Member
Sierra Vista Hospital Governing Board

cc: Senator Pete Domenici
Senator Jeff Bingaman
Representative Steven Pearce
Representative Heather Wilson
Representative Tom Udall
Senator John Arthur Smith
Senator Leonard Lee Rawson
Representative Diane Hamilton

Hefter
Hartstein
GEO Reclass - Kenly
W/I Miller
90

June 10, 2005

Impact - Kraemer

Bethesda Memorial Hospital

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Comment on the FY 2006 proposed Inpatient Prospective Payment System regulation regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications".

Dear Sir or Madam:

The purpose of this letter is to comment on the FY 2006 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications. GEO Reclass

Bethesda Memorial Hospital is a 362 bed not-for- profit hospital located in Palm Beach County, Florida, and like most South Florida hospitals, a significant percentage of our patient population consists of Medicare beneficiaries. Adequate Medicare reimbursement, therefore, is critical to our continuing ability to meet their needs.

Last year when the proposed wage index classification rule was published, we thought we had, for the first time, qualified for the opportunity to reclassify for wage index purposes, because the proposed rule had been broadened to allow more areas to qualify. We joined with all other Palm Beach County hospitals to evaluate this possibility and then applied for re-designation. The final rule, however, changed the proposed criteria and ultimately left us disqualified when the CBSA category was completely dropped.

We request that CMS revise the urban group reclassification eligibility criteria contained in the proposed FY 2006 IPPS regulation as follows (requested revisions are in bold print):

1. "Hospital's must be **in counties that are in the same Core-Based Statistical Area (CBSAs) that comprise metropolitan divisions or** located in counties that are in the same Combined Statistical Area (CSA) as the urban area to which they seek redesignation to qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation"

2. **"Areas will qualify as a CSA if the OMB designated the area as a CSA or if the area had qualified to elect to be designated a CSA, whether or not the area made that election".**

3. **The FY 2006 proximity criteria will be effective for urban group reclassifications beginning on October 1, 2005 if the urban area:**

- **Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;**
- **Met all of the non–proximity urban group reclassification criteria published in the FY 2005 final regulation;**
- **Had the application denied only because the urban area did not meet the FY 2005 proximity criteria;**
- **Meets the FY 2006 proximity criteria (described above items 1 and 2); and**
- **Would have had the application approved had the FY 2006 proximity criterion been published in the FY 2005 final regulation.**

We request that CMS include the revisions, as written above, in the FY 2006 final IPPS regulation.

2. BACKGROUND

A. The Prior Year Federal Fiscal Year End September 30, 2005 (FY 2005) Proposed Inpatient Prospective Payment System (IPPS) Regulation

The FY 2005 proposed inpatient prospective payment system (IPPS) regulation issued on May 18, 2004 supported allowing urban hospital groups located within a Core-Based Statistical Area (CBSA) to seek reclassification to another area within the same CBSA (that is, to another Metropolitan Division) (see Federal Register, May 18, 2004, page 28354). The eleven CBSAs, established by the Office of Management and Budget (OMB) in June 2003, eligible for this reclassification were Boston, Chicago, Dallas, Detroit, Los Angeles, San Francisco, Philadelphia, New York, Seattle, Washington D.C., and Miami. The Miami CBSA consists of the West Palm Beach, Fort Lauderdale, and Miami, Florida Metropolitan Divisions. Therefore, the hospitals within this CBSA could reclassify from one Metropolitan Division to another if they met the remaining application criteria. These new CBSAs, created in 2003 by OMB, had replaced Consolidated Metropolitan Statistical Areas (CMSAs) previously established by OMB in 1990.

B. The Prior Year FY 2005 Final IPPS Regulation

In response to public comments regarding the proposed regulation and that the adoption of CBSAs as the criterion for reclassification would disadvantage certain hospital groups, CMS expanded the number of areas eligible for reclassification in the final FY 2005 IPPS regulation (see Federal Register, August 11, 2004, page 49105). The reclassification eligible areas were expanded to include:

- counties located in the same Combined Statistical Area (CSA), a new category created by the OMB; and
- hospitals in counties located in the same CMSA, (a reinstatement of the previous OMB designation).

As a result, the final FY 2005 IPPS regulation expanded the number of reclassification eligible areas from the proposed eleven CBSAs to approximately one-hundred and twenty CSAs and CMSAs.

C. *The Impact the FY 2005 Final IPPS Regulation had on the West Palm Beach Metropolitan division*

Although the hospitals in the West Palm Beach Metropolitan division (West Palm Beach-Boca Raton-Boynton Beach, Florida area) were eligible for reclassification to another metropolitan division within the Miami CBSA under the FY 2005 proposed regulation, those same hospitals became ineligible for reclassification under the final FY 2005 regulation.

The hospitals located in the West Palm Beach Metropolitan division were ineligible for reclassification because:

- the West Palm Beach Metropolitan division is not currently automatically considered a CSA by the OMB;
- the West Palm Beach Metropolitan division was not previously considered a CMSA; and
- the final regulation removed allowing urban hospital groups located within a CBSA to seek reclassification to another area within the same CBSA (that is, to another Metropolitan Division).

The hospitals in the West Palm Beach Metropolitan division, based on the FY 2005 proposed regulation, submitted an application to CMS for a reclassification beginning October 1, 2005. CMS denied the application citing that the hospitals in the West Palm Beach Metropolitan division did not meet the criteria contained in the final regulation. The hospitals have appealed the CMS denial to the Medicare Geographic Classification Review Board (MGCRB).

We understand that the change in criterion between the FY 2005 proposed and final regulation (from the eleven CBSAs that comprise metropolitan divisions to CSAs and CMSAs) was to be more inclusive regarding what areas qualified. However, the West Palm Beach metropolitan division did not qualify under the final FY 2005 regulation but did under the proposed regulation (not more inclusive for the West Palm Beach metropolitan division). We do not believe CMS intended to exclude the West Palm Beach metropolitan division from eligibility in the final FY 2005 regulation; it was likely an oversight. In fact, it is our understanding that the other ten CBSAs that comprise metropolitan divisions qualified as CSAs or CMSAs and were not harmed by the change from the proposed FY 2005 to the final FY 2005 regulation. Only the West Palm Beach metropolitan division was harmed.

We believe it was the intent of CMS to also include the new CBSAs that comprise metropolitan divisions in the final FY 2005 regulation eligible criterion (along with CSAs and CMSAs). The OMB, in 2003, created the new CBSAs that comprise metropolitan

divisions to replace the outdated CMSAs previously established by the OMB in 1990. We feel CMS intended to include both of the new OMB area definitions in the final FY 2005 regulation (CSAs and CBSAs that comprise metropolitan divisions) not the one outdated CMSA area definition. At the very least, CMS should have included all three area definitions (CSAs, the outdated CMSAs, and the new CBSAs that comprise metropolitan divisions) in the final FY 2005 regulation eligible criterion.

Also, the application for urban group reclassification was due to be filed by September 1, 2004. The final FY 2005 regulations were not published until August 11, 2004. The hospitals in the West Palm Beach Metropolitan Division could not have waited until the final regulations were published on August 11, 2004 to organize the entire county knowing that the application was due to be sent only 20 days later, on August 31, 2004. It is a very complex process to organize what are normally competitive organizations to join a common initiative. It takes much longer than 20 days. Therefore, based on the FY 2005 proposed regulations and the fact that the hospitals in the metropolitan division were eligible for an urban group reclassification, tremendous efforts and costs were invested by the hospitals in the West Palm Beach Metropolitan Division to achieve a county-wide reclassification.

3. THE FEDERAL FISCAL YEAR END SEPTEMBER 30, 2006 PROPOSED IPPS REGULATION

A. Urban Group Hospital Reclassifications

The FY 2006 proposed IPPS regulation proposes to delete the reference to the CMSA urban group reclassification criterion. The regulation states in part that "beginning with FY 2006, it is proposed to require that hospitals must be located in the counties that are in the same Combined Statistical Area (CSA) as the urban area to which they seek redesignation to qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation".

4. REQUESTED REVISIONS TO THE FY 2006 PROPOSED IPPS REGULATION AND ISSUES TO BE CONSIDERED IN THE FY 2006 FINAL IPPS REGULATION

A. Allow hospitals that are located in counties that are in the same Combined Statistical Area (CSA) OR IN THE SAME CORE- BASED STATISTICAL AREA (CBSA) THAT COMPRISE METROPOLITAN DIVISIONS as the urban area to which they seek redesignation to qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

The FY 2006 proposed regulations regarding urban group reclassifications and the removal of CMSAs as urban group reclassification criterion state in part that "based on our experiences now that the new market areas are in effect and since we revised the urban county group regulations, we no longer think it is necessary to retain the use of a 1990-based standard as a criterion for determining whether an urban county group is eligible for reclassification. We believe it is reasonable to use the area definitions that are based on the

most recent statistics; in other words, the CSA standards". The proposed regulation goes on to state that "we believe that this proposed change would improve overall consistency of our policies by using a single labor market area definition for all aspects of the wage index and reclassification".

We disagree that the CSA standards alone are the most recent statistics and standards. It is clear throughout the proposed FY 2006 and FY 2005 regulations and the final FY 2005 regulations that the eleven CBSAs that comprise metropolitan divisions are also the most recent standards and statistics, as recent as CSAs. In fact, the eleven CBSAs that comprise metropolitan divisions were intended by the OMB to replace the outdated CMSAs. The same CMSAs that CMS proposes to remove from the criterion as outdated; yet, CMS does not propose to replace the CMSAs in the criterion with the most recent standard and statistic recognized by the OMB for like areas, the eleven CBSAs that comprise metropolitan divisions.

We believe that CMS should include both CSAs and the eleven CBSAs that comprise metropolitan divisions in the qualifying criterion in order to consider all of the most recent and appropriate area designations, statistics and standards as CMS intends in the proposed regulation.

We also disagree that this proposed change to include only CSAs in the criterion provides and improves the overall consistency of the CMS policy by using a single labor market area definition for all aspects of the wage index and reclassification. We believe that the CSA designation and standard is only utilized for purposes of this urban reclassification proximity criterion and not for any aspects of the wage index or other type of reclassification or redesignation. Therefore, including the eleven CBSAs that comprise metropolitan divisions in the qualifying criterion will not have a negative impact on the overall consistency of the CMS policy.

If CMS intends to use the area definitions that are based on the most recent statistics and to improve the overall consistency of their policies to determine the proximity criterion, as the proposed regulation states, then both CSAs and CBSAs that comprise metropolitan divisions must be considered in the proximity criterion.

B. Allow areas to qualify as CSAs if the OMB designates the area as a CSA or if the area has the ability to elect to be designated a CSA, whether or not the area made that election.

We understand, through review of the August 22, 2000 Federal Register and discussions with OMB staff, that the criteria for an area to "automatically" be considered a CSA is when the employment interchange (commuting) measure between adjacent CBSAs is at least 25%. Also, adjacent CBSAs that have an employment interchange measure of at least 15% and less than 25% will combine as a CSA if local opinion, as reported by the congressional delegations in both areas, favors combination. The Federal Register states that the OMB will seek local opinion regarding the CBSA combination (CSA). The Federal Register also states that after a decision has been made regarding the CBSA

combination (CSA), the OMB will not request local opinion again on the issue until the next redefinition of CBSAs.

We also understand, through discussions with OMB staff, that although the OMB is to seek local opinion regarding CSA combination, no formal OMB policy for seeking local opinion through congressional delegates is or was in place.

By allowing only adjacent CBSAs that automatically qualify as CSAs to meet the urban group reclassification criterion, CMS has taken the position that adjacent CBSAs that qualify for CSA election were contacted by the OMB (as the Federal Register states) to seek local opinion and the local opinion did not elect CSA combination. We believe the adjacent CBSAs that could elect CSA combination were never informed and local opinion never obtained.

We believe that because their was no formal OMB policy to seek local opinion on CBSA combination to elect CSA designation and the fact that there was opportunity for two adjacent CBSAs to be considered a CSA through an election, CMS should allow areas to qualify as CSAs if the OMB designates the area as a CSA automatically or if the area has the ability to elect to be designated a CSA, whether or not the area made that election.

5. CONCLUSION

Based on the aforementioned information we request that CMS incorporate the revisions, as written in section one of this document, in the FY 2006 final IPPS regulation. The requested revisions are critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and will effect payments to all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2005.

We appreciate your consideration of this comment to the FY 2006 proposed IPPS regulation.

Sincerely,

Robert B. Taylor, Jr.

Robert B. Taylor, Jr.
Vice President of Finance/CFO

CENTER FOR PAIN CONTROL

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C. M. SCHADE, MD, PhD, PE, PA
ABA BOARD CERTIFIED IN PAIN MANAGEMENT
FELLOW OF INTERVENTIONAL PAIN PRACTICE
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VT

May 27, 2005

RECEIVED
JUN 15 2005
BY:----------

Hefter
Hartstein
Triebel
Walz

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1500-P
P.O. Box 8011 Baltimore, MD 21244-1850

To Whom It May Concern:

Re: Rechargeable Medtronic Neurostimulators

Dear Sir:

I am a board certified Pain Medicine Physician and I have a PhD in Electrical Engineering and Computer Science. I have been implanting spinal cord stimulators (SCS) for 15 years. The treatment of low back pain requires the highest power levels of all SCS therapies. The rechargeable SCS is the most cost effective device for this therapy (better pain coverage and relief of pain with much longer device life).

It is very important to continue to provide the best care for our patients utilizing the latest technology. Unfortunately this technology comes at a cost that is typically higher than the previous technology but provides a substantial clinical advantage and improvement.

Rechargeable neurostimulators and Radio Frequency (RF) neurostimulators are distinctly different technologies:

- Radio Frequency – external power source; it is not rechargeable and the therapy ends immediately when the transmitter is removed from the implant site. Further there tends to be less patient compliance (i.e. skin break-down)
- Rechargeable – as it implies it is a rechargeable internal power source that requires a charge for a short period of time about every three to six weeks. Therapy and relief can be provided to the patient endlessly.

Rechargeable neurostimulators represent a significant clinical improvement over the existing technology:

- Rechargeable technology provides more treatment options for those patients requiring high energy stimulation. Prior to the introduction of the rechargeable neurostimulator a patients options were limited to:
    - Frequent neurostimulator replacement
    - Battery conservation which limited the full benefit of the neurostimulation
- Reduction in surgeries related to neurostimulator replacement due to battery depletion.

While I understand the desire to control costs to CMS in this era of an aging population, the technologies (such as the rechargeable neurostimulator) that are coming out may have a higher up-front expense but the end result will be less surgical and physician encounters, thus providing a savings throughout the entire treatment cycle and saving CMS hundreds of thousands of dollars.

I appreciate your consideration of this DRG add-on payment and APC pass-through for this new technology.

Sincerely,

C.M. Schade, M.D. Ph. D.
Board Certified in Pain Medicine
Board Certified in Anesthesiology
Senior Disability Analyst and Diplomate

CMS/sll

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UW Medicine
SCHOOL OF MEDICINE

NT

Heart, Heart Valve, Tricuspid, Mitral

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June 3, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1500-P
PO Box 8011
Baltimore, MD 21244-1850

Re: Rechargeable Neurostimulators

To Whom It May Concern:

I write to urge the implementation of incremental hospital reimbursement for rechargeable neurostimulators in both inpatient and outpatient settings. This recent improvement in the technology available for the relief of chronic pain is a distinct advantage over prior devices. It offers those who suffer from chronic pains such as failed back surgery syndrome, complex regional pain syndrome, or neuropathic pain a far superior technology that will reduce the need for surgeries and the associated risks.

Prior neurostimulators were either fully implanted with no mechanism for recharging or replacing batteries without surgically implanting a new stimulator, or radio-frequency-coupled with a passive implanted device and an external pulse generator requiring the application of an antenna to the skin. Implanted neurostimulators have a battery life that is dependent upon usage patterns and may be as short as one year or as long as 7 years, but the average life in my experience has been 4 years. Radiofrequency-coupled devices cease working if the antenna is not correctly applied; many patients object to the need to wear an external stimulator device and the wire leading to the antenna. The external devices use a standard 9v battery that needs to be replaced, on average, weekly.

The new, rechargeable neurostimulators require a several hour period of recharging every few weeks and are expected to last for at least a decade. This will result in fewer surgeries to replace the neurostimulator with a reduction in both morbidity and cost, since every operation is associated with a small (~3%) infection rate. As someone who has implanted neurostimulators for thirty years, I have seen many improvements in the available technology. None, however, have represented as significant an advance as a rechargeable system.

A typical patient whom I care for has had three operations on his low back and remains disabled by his pain. Quality of life is poor and the patient spends much of his time seeking health care. Some of these patients get wonderful relief of their pain with a neurostimulator and are able to reduce medication consumption and stop seeking health care. Now we can implant a rechargeable neurostimulator and not

have to deal with the problems of stimulator failure and replacement that typically occur in three to four years. This will reduce the need for the patient to see me and to have operations for stimulator replacement. Rechargeable neurostimulators are a significant step forward and deserve improved reimbursement, as they cost significantly more than the existing technology.

I am happy to answer any further questions.

Yours truly,

John D. Loeser, M.D.
Professor of Neurological Surgery and Anesthesiology
University of Washington

Main Line Health
Louis E. Samuels, MD, FACS

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Louis E. Samuels, MD, FACS
Director Cardiac Transplantation
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Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
Attn: CMS-1500-P
PO Box 8011
Baltimore, MD 21244-1850

June 10, 2005

To Whom It May Concern:

As a Cardiothoracic Surgeon with sub-specialization in Heart Failure, I am acutely sensitive to the demands that confront us as the epidemic of cardiovascular disease continues to increase. Although tremendous advances have been made in the medical and percutaneous interventional therapies to treat decompensated heart failure, there are a proportion of patients that require advanced surgical treatments to save lives. The Ventricular Assist Device (VAD) is among the most important therapies to address the sickest group of patients as it relates to heart disease.

Mechanical cardiac assist technology comes in a variety of forms: there are internal electric units, external pneumatic units, devices to bridge patients to transplant, devices to used as permanent therapy, and devices to allow the heart to recover. It is the last form of device that I wish to comment on. The Bridge-to-Recovery device has been available to patients in the United States for over a decade. Tremendous achievements have been made with respect to patient selection, implantation technique, and post-implant management. In addition, improvements in pump design have made the devices safer and more durable. As a result, I have personally witnessed improved outcomes in this subset of patients. My own clinical research and experience, for example, have enabled me to improve the survival rate from 25% (national average) to nearly 50%. It is of interest to note that every patient supported on this technology would have expired without it. Therefore, every survivor is a very meaningful event.

Unfortunately, the reimbursement rates for the technology that supports Bridge-to-Recovery is inadequate. The original data from a decade ago is not reflective of what we are experiencing now. For example, we have learned that the average duration of support to recover the failed heart (and the other organ systems that went with it, such as the liver, gut, kidneys, and lungs) is about a month—not the 5-7 days that was previously believed. We have learned that the myocardium and the other organ systems need more time to fully recover such that a favorable outcome will be achieved once the VAD is removed. In the past, we were frustrated by the successful removal of the VAD at one week with subsequent and

rapidly fatal recurrence of acute heart failure shortly thereafter. Our recent experience has supported the better outcomes seen in longer term support to provide *sustained recovery*. However, in view of this, the hospital costs and charges far exceed the reimbursement to the extent that the use of the VAD for recovery is being questioned on a financial basis and not a clinical one. The result can lead toward two dangerous things: non-use of the appropriate therapy (i.e. The external VAD) or misuse of an alternative therapy (ie. The internal VAD—which is more favorably reimbursed). As a physician-surgeon, I shutter to think that the most appropriate therapy is not being applied for any reason, financial or otherwise. In my mind, it would be highly inappropriate to put an implantable VAD into someone who may recover their own heart. Just for clarification, the implantable VAD is really designed as either a Bridge-to-Transplant or Permanent Therapy—it is not realistically a Bridge-to-Recovery system since the implantable VAD requires the removal of some of the left ventricle to attach it—furthermore, explanting an implantable VAD is quite formidable, unlike the external VADS.

In conclusion, I feel very strongly about doing something to better match the reimbursement for the external VAD to cover the costs and charges associated with it. There are a lot of acute myocardial infarction patients in the United States—a subset develop cardiogenic shock—not all of them need to die and not all of them need a transplant. On the contrary, we have the technology to not only save their lives, but to allow them to keep their own hearts. The energy and the resources we put forth in our hospitals to save those lives are impressive. We would appreciate the US Government's support in continuing that effort.

Thank you very much.

Louis Samuels

Louis Samuels, MD, FACS
Surgical Director of Heart Failure & Transplantation
Director of the Artificial Heart & Ventricular Assist Device Program

NT - TREITEL
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W. L. GORE & ASSOCIATES, INC.
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June 17, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Subject: Section II.E.4.d. "Endovascular Repair of the Thoracic Aorta" (ERTA); consideration for FY 2006 IPPS New Medical Service and Technology status

As the applicant for "New Technology" status for ERTA, W.L. Gore and Associates is pleased to offer comments as solicited in the NPRM published May 04, 2005.

BACKGROUND

Section 533 of Public Law 106-554 directs Medicare to establish a mechanism for ensuring adequate payment for new medical services and technologies. This directive addressed two concerns; facilitating access to new technologies for Medicare beneficiaries, and to more expeditiously incorporate new services and technologies into the prospective payment system. The mechanisms subsequently established by regulation utilize three criteria to assess the qualifications of a service or technology for "add-on" payments:

- The service/technology must be "new", relative to current services/technologies
- The DRG prospective payment rate applicable to such service/technology is inadequate based on estimated costs of the new service/technology
- The diagnosis or treatment of Medicare patients is substantially improved, relative to technologies previously available

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Gore's "New Technology" application of October 2004 preceded FDA market approval in March 2005 of the GORE TAG® Thoracic Endoprosthesis ("TAG"); the Gore TAG device is the first technology approved for ERTA service. The following comments supplement that application, and include a summary of additional information relative to "cost" as requested by Medicare during the application review process.

COMMENTS

"New" Criteria

Endovascular Repair of Thoracic Aortic Aneurysm (TAA) with an approved device should be considered as a new service, effective no later than October 01, 2005 (FY 2006).

Discussion - Medicare has previously defined the "newness" of a technology as commencing with "...the availability of the product on the market"[1]. Consistent with that definition, and considering other factors used to assess "newness", ERTA would be "new" no earlier than April 2005, and no later than October 2005.

- FDA approval of TAG: March 23, 2005[2] (first device approved for this clinical application[3])
- First commercial sales of TAG: April 2005
- Implementation of ICD-9 39.73 *Endovascular implantation of graft in thoracic aorta*, October 1, 2005[4]

[1] Federal Register vol. 69, No. 154. Wed. August 11, 2004; p. 49003
[2] FDA approval P040043, posted March 23, 2005
[3] "*The Gore TAG Approval*", Abel, D.; Endovascular Today, April 2005; pp 65-66
[4] FY 2006 Final Addenda, ICD-9 CM Volume 3, Procedures; posted May 25, 2005

Cost Criteria

Endovascular Repair of the Thoracic Aorta for aneurysm (441.2), with the TAG device, has a conservatively estimated standardized charge of $52, 428; this exceeds the DRG-weighted threshold amount of $49,817. Thus, ERTA for aneurysm meets the" new-cost" criteria as established in regulation, and add-on payments will help reduce financial disincentive, as contemplated in the public law. DEG

Discussion- Based on 185 claims summarized in the October 2004 New Technology application, the average charge per discharge for ERTA of all diagnoses is $77,064 (standardized $60,905); versus the weighted threshold for DRG 110 and 111 of $49,817 (DRG 110/111, representing 96% of cases). Identification of claims was accomplished using primary procedure 39.79 linked to any one of the three major thoracic aortic diagnoses, a claim identification technique used by Medicare in previous analysis of new technology issues[5]. All claims identified during this pre-approval time period represent services provided in clinical trial settings. Hospital charging practices for clinical trial services are known to vary, with some institutions not charging for IDE devices, or charging with reduced or no mark-up. This practice would tend to make the estimated average charge conservative.

MedPAC has also urged a "conservative approach" in evaluating technologies for add-on payments[6] , and in assessment of prior applications, Medicare has considered only data from cases that would be "consistent with the FDA's approval"[7]. For repair of the thoracic aorta, diagnosis 441.2 best describes the FDA indications for the recently approved TAG device. As a subset of the cases presented in the New Technology application for ERTA, 127 cases (69%) were associated with primary diagnosis 441.2, with an average charge of $67, 853 (standardized charge of $52,428). This more restrictive approach indicates that standardized charges still exceed the threshold amount required for add-on payment.

Subsequent to the October 2004 application, Medicare requested a sample of hospital UB-92 claims for review, in order to understand in greater detail how endovascular repair impacts the major categories of hospital resources[8]. Twenty-one claims were available for this "validation sample", from three geographically dispersed institutions where the Gore TAG device was utilized under IDE clinical trial status. Thirteen of these cases were performed on patients with a 441.2 diagnosis, with Medicare as a payer. Eliminating one high-charge case (involved interventions unrelated to the TAA), the average charge of the remaining 12 case "validation sample" was $77,607 (standardized charge $52, 777). This compares favorably with analysis done using the larger Medpar dataset, and further confirms the conservative nature of the analysis submitted in the New Tec application.

Table 1: Summary of Charges and Standardized Charges for ERTA

Source	Primary Diagnoses	Discharges	Avg. Charge	Avg. Std. Charge*
Oct 2004 New Tec App. (2003 Medpar)	441.2, 441.1, 441.01	185	$77,064	$60,905
	441.2	127	$67,853	$52,428
"Validation" Sample	441.2	12	$77,607	$52,777
Estimated Threshold	DRG 110/111 (96%)	177 (153/24)	$73,267	$49,817

*All Standardized Charge Calculations by the Moran Company, Arlington, VA

In discussing the reduction of the regulatory threshold cost criteria for FY 2004 'New Technology" applications, Medicare explained that "Add-on payments are intended to give technologies a competitive boost relative to existing treatment methods with the goal of encouraging faster and more widespread adoption of new technologies."[9] This goal is especially meaningful with ERTA, where not only the magnitude but the types of costs have important financial implications for the hospital. Endovascular technology represents a significant shift of hospital cost to purchased medical/surgical supply (devices) and away from resources such as critical care nursing, monitoring and room costs that dominate the traditional open surgical procedure. Add-on payments will help hospitals accommodate this shifting of resources during the transitional period from labor-intensive to technology intensive case loads, and will reduce constraints to access.

[5] Federal Register vol 69, No. 154, Wed. Aug 11, 2004, p49014
[6] Federal Register vol. 69, No. 154, Wed. Aug 11, 2004, p.49011
[7] Feral Register vol. 68, No. 148, Friday August 1, 2003, p. 45390
[8] Personal Telecon w/J. Kelly, MD; M. Walz; CMS
[9] Federal Register vol. 68, No. 148, Friday August 1, 2004, p 45392

"Clinical Improvement" Criteria

Endovascular Repair of the Thoracic Aorta with the Gore TAG device provides an efficacious alternative to traditional open surgery, as demonstrated by clinical study. Patients treated with the TAG device had a greater probability of remaining free from major adverse events than patients treated with open surgical repair. Secondary benefits include reduced blood loss, ICU/ total hospital stay, and faster return to normal activity.

Discussion - Medicare has previously confirmed that an important criterion for substantial clinical improvement is avoidance of surgery[10]; provided that an equivalent outcome (efficacy) has been demonstrated. The Gore TAG device was the subject of two US FDA Clinical Studies conducted to evaluate safety and effectiveness as an alternative to traditional open surgery, culminating in FDA approval in March, 2005 (PMA number P040043). Data from these clinical trials were included in the October "New Tec" application; and are summarized in the tables below. (Tables as presented in the Instructions for Use for the GORE TAG THORACIC ENDO PROSTHESIS).

Table 2: Major Adverse Events from US Clinical Trial (source: Table 1, p. 4, IFU)

	Post-treatment follow-up period (days)						
	0 - 30			31 - 365		366 - 730	
Safety endpoints	TAG 99-01 (N = 140) n (%)	TAG 99-01 Control (N = 94) n (%)	TAG 03-03 (N = 51) n (%)	TAG 99-01 (N = 134) n (%)	TAG 99-01 Control (N = 85) n (%)	TAG 99-01 (N = 106) n (%)	TAG 99-01 Control (N = 66) n (%)
All-cause deaths	2 (1)	6 (6)	0	22 (16)	14 (16)	10 (9)	4 (6)
Aneurysm related deaths	2 (1)	6 (6)	0	2 (1)	3 (4)	0	0
Any major adverse event	40 (29)	66 (70)	6 (12)	37 (28)	22 (26)	15 (14)	6 (9)
Bleeding complications	13 (9)	50 (53)	0	3 (2)	1 (1)	2 (2)	0
Pulmonary complications	9 (6)	31 (33)	2 (4)	13 (10)	8 (9)	6 (6)	0
Cardiac complications	4 (3)	19 (20)	1 (2)	18 (13)	7 (8)	7 (7)	2 (3)
Renal function complications	2 (1)	12 (13)	0	4 (3)	3 (4)	1 (1)	0
Wound complications	8 (6)	11 (12)	1 (2)	1 (1)	3 (4)	1 (1)	1 (2)
Bowel complications	3 (2)	6 (6)	0	3 (2)	0	1 (1)	0
Vascular complications	20 (14)	4 (4)	3 (6)	5 (4)	2 (2)	0	0
Neurologic complications	11 (8)	30 (32)	1 (2)	4 (3)	4 (5)	3 (3)	1 (2)
Other major complications*	0	1 (1)	1 (1)	2 (1)	2 (2)	0	0
Reoperation	4 (3)	0	0	2 (1)	0	0	0
Rupture	0	0	0	0	0	0	0

Note: The difference between the TAG 99-01 and TAG 99-01 Control groups for any major adverse event at 1-year is statistically significant ($p<0.001$).

The difference between the TAG 03-03 and TAG 99-01 Control groups for any major adverse event at 30 days is statistically significant ($p<0.001$).

*aortoenteric fistula, prosthesis infection

[10] Federal Register vol. 68, No. 148, Friday august 1, 2003, p 45391

Table 3: Secondary Endpoints (source:Table 19, p. 14, IFU)

Endpoint	TAG 03-03	TAG 99-01	TAG 99-01 Control	TAG 99-01 vs. TAG 99-01 Control p-value[1]	TAG 03-03 vs. TAG 99-01 Control p-value[1]
Blood loss during procedure (ml)	222.4 ±198.0 (n = 51)	471.9 ±862.7 (n = 132)	2402 ± 2719 (n = 52)		
Length of ICU stay (days)	1.2 ± 1.3 (n = 51)	2.7 ± 14.6 (n = 136)	5.2 ± 7.2 (n = 91)	< 0.001	< 0.001
Length of hospital stay (days)	4.8 ± 5.0 (n = 51)	7.4 ± 17.7 (n = 139)	14.4 ± 12.8 (n = 91)	< 0.001	< 0.001
Time to return to normal daily activities (days)	18.5 ± 15.9 (n = 42)	60.2 ± 82.7 (n = 114)	149.2 ±201.0 (n = 51)		
[1] no test of significance due to high proportion of surgical (TAG 99-01) missing data.					

SUMMARY

The Endovascular Repair of Thoracic Aorta, when performed with FDA-approved endovascular devices, should be awarded "New Technology" status. This service meets the intent of the public law in establishing the IPPS new technology provision, and meets criteria established in regulation for qualifying these new technologies.

Thank you for considering these comments.

Best Regards,

Don Goffena
W.L. Gore and Associates, Inc.

Attachments:
"The GORE TAG Approval- what took so long?" April 2005 Endovascular Today

The Gore TAG Approval

What took so long?!

BY DOROTHY B. ABEL

The views and opinions presented in this article are those of the author and do not necessarily reflect those of the US FDA, the US Department of Health and Human Services, or the Public Health Service.

For many years, the FDA has received patient, clinician, and even congressional inquiries as to why we had not yet approved an endovascular graft for treatment of thoracic aortic aneurysms. The potential for significant improvement in patient care for those with thoracic aortic aneurysms was clear to all. So what took so long? Some candid answers follow.

We cannot approve a PMA before one is submitted.

Although the potential benefits of endovascular repair of thoracic aortic aneurysms was clear, valid scientific evidence (ie, data) had to be collected to demonstrate that a specific endovascular graft was reasonably safe and effective for this indication. This required both non-clinical and clinical evaluations. As with endovascular grafts for treatment of abdominal aortic aneurysms (AAAs), 1-year clinical data on a statistically justified number of nonrandomized patients were needed.

> "1-year clinical data on a statistically justified number of nonrandomized patients were needed."

Many may argue that these data have been available for quite some time. Regardless, if a PMA was not submitted based on these data, we could not approve the device.

Once the Gore TAG PMA was submitted, we had to conduct a scientific review.

PMAs have a 180-day review cycle. This cycle starts with a filing review during which all of the members of the review team look over the submission to determine whether adequate information has been provided to allow for a substantive review. The sponsor should be notified as to whether its PMA is filed within 45 days of the receipt of the PMA. We then complete our review; identify any questions or concerns, communicate them to the sponsor, and attempt to resolve the issues with the sponsor. This entire process should be completed well in advance of the FDA advisory panel meeting to optimize the panel discussions.

For the Gore TAG (W. L. Gore & Associates, Flagstaff, AZ) PMA, the panel meeting was held January 13, 2005, only 3 months after receipt of the file. Examples of interactions for the Gore PMA included our request for a propensity score analysis to take a closer look at whether there were any differences in the patient populations enrolled in the various arms of the study and clarification regarding the corrosion properties of the metallic components of the implant. These and other concerns raised during our review of the PMA were presented at the panel meeting as part of our briefing on our review findings.

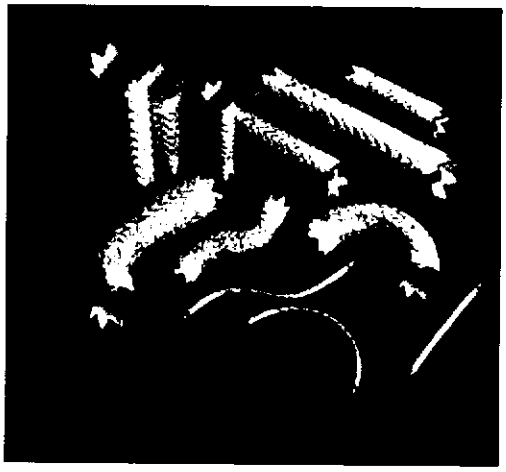

Figure 1. The Gore TAG Thoracic Endoprosthesis.

After the panel meeting, we had to complete the close-out process.

The panel recommended approval with conditions in

January, but the approval was not granted until March 23, 2005. The time between the panel meeting and final approval was primarily spent finalizing the labeling and the summary of safety and effectiveness data, as well as establishing the conditions of approval.

This was a first-of-a-kind approval, with only the AAA endovascular grafts providing partial precedent. Although some warnings and precautions are generic to all endovascular grafts used to treat aneurysms, specific concerns related to thoracic repair had to be incorporated in the product labeling. Similarly, although some of the conditions of approval were comparable to the AAA devices, others had to be specifically crafted for this PMA.

> "Sponsors of future PMAs may or may not need to go before the advisory panel."

The comparable conditions included the need to follow IDE subjects (approximately 400 patients) through 5 years of follow-up and provide clinical updates to device users on an annual basis. A new requirement was a postapproval study requiring enrollment of an additional 150 patients with descending thoracic aortic aneurysms at 35 geographically separate sites. This study will provide an assessment of the training program by comparing the results for these patients to those enrolled under the IDE.

The postmarket patients are also to be followed through 5 years postimplant. In addition, the sponsor has been requested to increase the size of the surgical control group through a comprehensive literature review. The combination of IDE and postmarket patients will provide adequate numbers to determine whether the reduction in aneurysm-related mortality associated with the Gore TAG device observed in the IDE is maintained post-approval.

The new requirements for the Gore TAG device as compared to the AAA devices resulted from the transfer of the Conditions of Approval (CoA) Study program from the Office of Device Evaluation (ODE) to the Office of Statistics and Biometrics (OSB). For first-of-a-kind products such as the Gore TAG device, epidemiologists at OSB will be working with the sponsors to incorporate statistical methods into the CoA studies to improve the scientific rigor of these studies. Additional information regarding this transfer of responsibilities is to follow in a separate article.

This PMA sets the standard for future PMAs for endovascular grafts intended to treat descending thoracic aneurysms.

The Gore TAG device was approved less than 180 days after the PMA was received. It is difficult to envision approval of future endovascular grafts for the treatment of descending thoracic aortic aneurysms to be completed in less time. Often files are put on hold while issues are being addressed, something that did not happen with the Gore PMA. Even if the file is not put on hold, there are almost always clinical and/or nonclinical questions that require a significant amount of time for the sponsor to address.

New applicants will benefit, however, by using the W. L. Gore & Associates experience in writing their PMAs and device labeling. Future sponsors should proactively incorporate information to address issues raised at the Gore TAG panel in their PMAs. In addition, they should use the Gore TAG labeling as a template when writing their labels, as many of the warnings and precautions are relatively generic and may also apply to their device.

Sponsors of future PMAs may or may not need to go before the advisory panel. If no new issues are identified in their submission; that is, if the concerns are consistent with those already discussed by the panel, panel review would be unnecessary.

Indications other than treatment of descending thoracic aneurysms may be approved in the future.

Now that W. L. Gore & Associates has an approved PMA for an endovascular graft for use in the thoracic aorta, they could possibly submit a PMA supplement to change their labeling to include treatment of other etiologies, such as aortic dissections and transections. Such a supplement could be panel tracked, meaning that panel input may be obtained in the review of the file. Clearly, these indications would need to be discussed by a full panel if a new device were to come in under PMA without a prior approval for treatment of descending thoracic aortic aneurysms.

Additional information on FDA Advisory Panels can be found in the November/December 2002 issue of *Endovascular Today*. Information on the PMA process can be found in the April 2004 issue of *Endovascular Today*. Each of these articles can be accessed electronically at http://www.evtoday.com/Pages/FDA.html ■

Dorothy B. Abel is a Regulatory Review Scientist with the US FDA Center for Devices and Radiological Health in Rockville, Maryland; she is also a regular columnist for Endovascular Today. *Ms. Abel may be reached at (301) 443-8262, ext. 165; dba@cdrh.fda.gov.*

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NAVAJO HEALTH FOUNDATION

SAGE MEMORIAL HOSPITAL
POST OFFICE BOX 457 / GANADO, ARIZONA 86505 / (928) 755-4500

June 13, 2005

CAH/Reloc - Collins
Morey
Smith
Hefter
Hartstein

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
PO Box 8011
Baltimore, Maryland 21244-1850

Reference: Medicare Program Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates.
42 CFR Parts 405, 412, 413, 415, 419, 422 and 485 (CMS 1500 P RIN 0938-AN 57-Proposed Rule.

Subject: Proposed Policy Changes Related to Designation of CAHs as Necessary Providers.

Dear CMS Rulemakers:

I am writing to express extreme concern about the above referenced proposed rule that would prevent the Navajo Health Foundation/Sage Memorial Hospital, located on the Navajo Reservation from either renovating or replacing its dilapidated Sage Memorial Hospital. In 2002 the Arizona Department of Health Services advised the NHF/SMH unless it had a definitive new construction/renovation project/plan in place or assured its hospital license would be revoked.

The first rudiments of healthcare began in 1901 being started by Presbyterian missionaries for the Navajo people of the service area. The first Sage Memorial Hospital was built in 1929. An all Navajo Board of Directors (eight members elected by the eight communities within the service area and two members appointed by the eight elected members) assumed ownership and directorship of Sage Memorial Hospital in 1974.

The current Sage Memorial Hospital was built in 1974 with a building by name of Poncel Hall being converted into an outpatient facility. The current hospital is constantly undergoing repairs and barely meets standards. The ADHS has granted continued operation of the hospital with the understanding that by February, 2006, construction will be in progress or construction ready to begin. A feasibility study for site selection has

been completed and the NHF/SMH Board of Directors will be selecting a site. Financial arrangements for the construction will follow very shortly upon the selection of a site.

The Sage Memorial Hospital with its ambulatory care component including outreach clinics has been the mainstay of health and medical care for many years and is truly a community based health care facility. In 2004, the Navajo Nation Council, voted to allow the Sage Memorial Hospital to contract as a "638" facility under the Indian Self-Determination Act. Closure of this hospital program would leave the community bereft of the health care facility which has looked after its health and medical care needs for many years and create real hardship for the Navajo people of the area who would have to seek care at other distant facilities (emergencies and obstetrical care particularly).

Two proposed rules are of extreme concern:

1. CMS proposed rule that will prevent critical access hospitals from rebuilding their facilities outside of a 250 yard limit of the current building. The Presbyterian Church owns the land on which the current hospital is located and it is reluctant to have a facility constructed on that property. The new site which would be outside of the church property and beyond the 250 yard limit but on Navajo land will be serving exactly the same population that the current program serves. The service area is an under served rural area. This rule would preclude any construction and the current hospital program would close.

2. CMS proposed rule that any critical access hospital designated under the necessary provider rules must demonstrate that construction plans were under way prior to December 8, 2003. The Sage Memorial Hospital was designated a Critical Access Hospital in late 2002/early 2003, shortly after the U. S. Congress approved the law that would grant such designations. The decision by the Board of Directors of Sage Memorial Hospital to build a replacement hospital was made at the time the Arizona Department of Health Services advised that some definitive action must be in place for new construction by February, 2006. In FY 2004, the Board of Directors dedicated $200,000 for the feasibility study to be conducted which has been completed. This retroactive ruling is patently unfair as funds and efforts have been expended to get the hospital replacement program underway. Prior to the decision to move forward with construction Sage Memorial Hospital was in no financial condition to embark on such an ambitious project but nonetheless the Board of Directors knew that that decision needed to be made. The mentioned feasibility study, review of our audits for the past three years by lending financial institutions and by federal agencies that would guarantee loans for construction have indicated that the project is feasible.
   With such possibilities at hand this ruling would entirely prohibit a needed facility that could readily be constructed from being constructed.

Sage Memorial Hospital and its Board of Directors, for the sake of the Navajo people residing the in the service area that will be affected and who look to SMH for their health

and medical care urges that this proposed ruling not be further considered and not be implemented.

Sincerely,

Taylor McKenzie MD

Taylor McKenzie, MD, Chief Executive Officer
Sage Memorial Hospital
Ganado, Arizona 86505
Ph. No. 928-755-4602
Fax: 928-755-4659

Cc: Richie Nez, President, Board of Directors
File

96

Rec'd 6/13/05 L.N.W.

CAH/Reloc - Collins Morey Smith

Osceola Medical Center™

June 1, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue
Washington, D.C. 20201

Dear Sir or Madam:

I am commenting on the proposed rule – CMS-1500-P – that would cause Critical Access Hospitals (CAH) to lose their CAH status if they build a replacement facility that is within 35 miles of another hospital.

Our hospital has purchased property a mile and a half from our current site and plans to build a replacement facility. The proposed rule would prevent us from doing that. Our hospital dates to the 1940s. We are running out of room because of the consistent growth we have seen. We are in a residential area immediately adjacent to a river and have no room to expand. As our community grows, we are running out of space to add additional physicians, new services and technology. We are also running short of basic services such as parking spaces. The building is inefficient and requires upgrading of the heating and cooling systems. However it makes no economic sense to make a significant investment in an aging building that cannot meet our space needs. CAH/Reloc

Our building needs to be replaced so we can continue to serve our community as it grows. When we move we intend to retain current services and staff. We strongly object to the provision of the rule that would remove CAH status from Necessary Providers that build a new facility greater than 250 yards from their current facility and request that that provision be eliminated. Thank you.

Sincerely,

Jeffrey K. Meyer

Jeffrey K. Meyer
Chief Executive Officer

301 River Street P.O. Box 218 Osceola, WI 54020 • (715) 294-2111 Fax (715) 294-3694
www.osceolamedicalcenter.com Toll Free: 1-888-565-4662

CMS-1500-P-181

CAH/Reloc Hefter, Hartstein Collins Morey Smith

Date: 06/08/2005

Submitter : Mr. Jason Anglin

Organization : Atoka Memorial Hospital

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

Comment on (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that have been designated as a Necessary Provider (NP).

I am writing as CEO of Atoka Memorial Hospital (AMH) and on behalf of rural residents. AMH is a 25 bed CAH located in rural south eastern Oklahoma. AMH was the first hospital in Oklahoma to be certified as a CAH and was certified as a ?necessary provider?.

AMH was built in 1959 (prior to major life safety codes enacted in the late 1960?s) and is in need of a new facility. Our 46 year old facility is outdated, inefficient to operate, lacks space for needed services, and hinders our ability to provided quality services. In addition land space is not available at our existing location. AMH had a feasibility study done on whether it was more economical to renovate and expand our existing facility or to build a new facility and it was determined that a new facility was more cost effective.

If it is more cost effective isn?t it logical to build a new facility rather than embark on a more expensive renovation? If you are land locked isn?t it reasonable to relocate a few miles to a feasible site within the community?

The proposed rule would prevent AMH from addressing our facility needs and the quality medical care needs of our community.

Why If AMH was certified as a ?necessary provider? would AMH not be a necessary provider if AMH relocated two miles to another site? AMH would still be servicing the same community.

CMS has taken an ill advised step which will result in rural communities being unable to obtain quality medical care. The proposed regulations place a ban on new construction for almost half of all small rural hospitals. Many of the small rural hospitals are now forty to fifty years old. These aging facilities are simply not capable of providing high quality, cost efficient service without the Necessary Provider Designation.

The proposed rule will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care. As inefficiencies are realized, CMS will be forced to provide more money to assets to maintain an aging and declining healthcare infrastructure in rural America. Ironically, the CMS proposal to ban a local community?s ability to rebuild on an adjacent or nearby location will cost Medicare more over time, not less. The higher labor costs of operating in a retrofitted building more than offset the cost of rebuilding. The proposal then displays a short sighted thinking process by the rule makers and a dramatic misunderstanding of the health care setting in rural areas.

The CMS proposed regulations reverse a long standing policy. Designation as a CAH necessary provider is associated with its current Medicare provider agreement which should remain intact unless the CAH fundamentally changes its business or is terminated by Medicare for cause. It is a longstanding policy that the provider agreement describes the legal entity and the services provided ? not the physical structure or location.

Based on the information presented above, my recommendation is that any CAH be allowed to replace or relocate their facility and maintain their status as a CAH as long as that facility can satisfy the 75% rule.

Specifically, I absolutely oppose any and all deadlines for actions related to Critical Access Hospital (CAH) replacement or relocation. The proposed ?75% threshold? is appropriate and sufficient to assure that a replacement or relocation CAH facility continues to meet the intent of its original Necessary Provider designation, i.e. that the ?CAH serves at least 75 percent of the same service area that it served prior to its relocation, provides at least 75 percent of the same services that it provided prior to the relocation, and is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees.?

98
Hefter
Hartstein
Collins
Money
Smith

CAH/Reloc

Submitter : Mr. Paul Cunningham **Date:** 06/13/2005

Organization : Arkansas Hospital Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

I am writing in regard to the proposed rule?s changes in the requirements for critical access hospitals (CAH), which set very restrictive guidelines for the replacement/ relocation of those facilities. As you know, the current rule allows critical access hospitals to receive reimbursements from the Centers for Medicare and Medicaid Services (CMS) at 101% of their cost rather than being paid under the Medicare?s prospective payment system. Rural hospitals are eligible to be designated as a CAH if they have 25 or fewer acute-care beds, have an average length of stay less than 96 hours, and are located at least 35 miles from another hospital.

Converting to CAH status has literally been a lifesaving move for rural towns and their hospitals.
Arkansas has 23 critical access hospitals. All are located in remote areas of the state and are the sole providers of inpatient acute-care services and offer outpatient and long-term care services in their communities. Many operate in buildings originally constructed with financing provided through the old Hill-Burton program, meaning they are 40-50 years old. Those facilities have needed for many years to be replaced. Prior to obtaining CAH status, replacement or relocation was not possible because the hospitals simply could not afford the major expense involved. The more favorable financing available through the CAH program now allows communities where those hospitals are located the hope of more modern hospital facilities.

Improved facilities would allow the addition of fire and smoke barriers and other life and fire safety code updates, infrastructure upgrades and other safety measures. However, building a replacement hospital in many of the communities means moving to another location, since the current hospital is either landlocked or needs to relocate to improve both site safety and quality of care. The proposed rule takes away this option in places it is most needed.

The Medicare Modernization Act of 2003 (MMA), beginning January 1, 2006, removes the ability of states to certify hospitals that are within 35 miles of another hospital as necessary providers, qualifying them as CAHs, but it grandfathers existing CAHs within the distance limit, allowing them to keep their CAH status. The proposed rule could prevent any CAH with necessary provider status from relocating its facility if it moves no more than 250 yards from the existing location, unless it can demonstrate that its construction plans began prior to December 8th, 2003.

We believe this arbitrary distance requirement will do great harm to CAHs and rural communities in Arkansas. It will force communities to choose between remaining in and maintaining older hospital facilities (which will most likely cost Medicare more, not less, over time because the higher costs of operating in an outdated building more than offset the cost of rebuilding), or building new hospitals and losing their CAH status. Neither choice is acceptable.

When CMS originally allowed states the authority to designate hospitals as medically necessary and waive the 35-mile CAH limit, it was for all the right reasons. Yet, with the mere stroke of a pen, CMS could tag those hospitals as no longer necessary for all the wrong reasons.

The Arkansas Hospital Association objects to the Rule?s change regarding CAHs and asks that CMS delete it.

Duplicate Letter SAME AS #98

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CMS-1500-P-324 and CMS 1500-P

129

CAH Reloc

Submitter : Mr. Paul Cunningham **Date:** 06/13/2005

Organization : Arkansas Hospital Association

Category : Other Association

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-324-Attach-1.DOC – received

CMS-1500-P-324-Attach-2.DOC – blank page

See E-Comment # CMS-1500-P

99

Submitter : Ms. Debbie Howe **Date:** 06/08/2005

Organization : Weatherford Hospital Authority

Category : Critical Access Hospital

CAH/Reloc

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
PO Box 8011
Baltimore, MD 21244-1850

June 7, 2005
Reference: CMS-1500-P

Via e-mail: cms.hhs.gov/regulations/ecomments "Critical Access Hospitals"

To Whom It May Concern:

Comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that have been designated as a Necessary Provider (NP).

As the CEO, for Weatherford Hospital Authority dba: Southwestern Memorial Hospital located in Weatherford OK let me assure you our facility will suffer a great loss if the proposed rule is adopted as follows:

A recent proposed rule (Inpatient PPS) from the Centers for Medicare and Medicaid Services (CMS) provides that any Critical Access Hospital (CAH) designated as a ?necessary provider (NP)? by the State is prohibited from building a replacement facility unless: (1) It?s within 250 yards or on land owned before 12/08/03, (2) construction plans were started before 12/08/03, and (3) the new facility will provide care to at least 75% of current patients using at least 75% of existing staff (75% rule). The penalty for violating these regulations is an automatic loss of both CAH certification and cost-based reimbursement. Over 50% (600) of all CAH?s are ?necessary providers?.

We are completing plans for the construction of a Replacement Hospital. The community of Weatherford, OK passed a limited sales tax in which the Hospital will receive 2.25 million to be used in constructing or loan for constructing the New Hospital. A generous citizen has donated 20 acres with direct access frontage property off I-40. The location is 1.1 miles East of our current location. The Weatherford Regional Hospital Foundation as of June 7, 2005 has collected in cash and pledges over $2.million in private funds with a goal of $3 million to be allocated to the New Hospital. The total project is 16.5 million and the remainder to be financed by Hospital Revenue. The ability to payback the loan hinges greatly on our being able to retain our status as a CAH Hospital. Our project is targeted to begin construction in January 2006. Although we do plan to continue to use the current location for some services such as Accounts Payables, Payroll, Sleep Center Expansion and possible In-patient Physical Rehab the main Hospital will be at the new location. Please consider allowing current CAH to retain the status in a new location.

Respectfully,
Debbie Howe, CEO

Attachment #324

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1859

Dear Sir:

I am writing for the Arkansas Hospital Association in regard to the proposed rule's changes in the requirements for critical access hospitals (CAH), which set very restrictive guidelines for the replacement/ relocation of those facilities. As you know, the current rule allows critical access hospitals to receive reimbursements from the Centers for Medicare and Medicaid Services (CMS) at 101% of their cost rather than being paid under the Medicare's prospective payment system. Rural hospitals are eligible to be designated as a CAH if they have 25 or fewer acute-care beds, have an average length of stay less than 96 hours, and are located at least 35 miles from another hospital. Converting to CAH status has literally been a lifesaving move for rural towns and their hospitals.

Arkansas has 23 critical access hospitals. All are located in remote areas of the state and are the sole providers of inpatient acute-care services and offer outpatient and long-term care services in their communities. Many operate in buildings originally constructed with financing provided through the old Hill-Burton program, meaning they are 40-50 years old. Those facilities have needed for many years to be replaced. Prior to obtaining CAH status, replacement or relocation was not possible because the hospitals simply could not afford the major expense involved. The more favorable financing available through the CAH program now allows communities where those hospitals are located the hope of more modern hospital facilities.

Improved facilities would allow the addition of fire and smoke barriers and other life and fire safety code updates, infrastructure upgrades and other safety measures. However, building a replacement hospital in many of the communities means moving to another location, since the current hospital is either landlocked or needs to relocate to improve both site safety and quality of care. The proposed rule takes away this option in places it is most needed.

The Medicare Modernization Act of 2003 (MMA), beginning January 1, 2006, removes the ability of states to certify hospitals that are within 35 miles of another hospital as necessary providers, qualifying them as CAHs, but it grandfathers existing CAHs within the distance limit, allowing them to keep their CAH status. The proposed rule could prevent any CAH with necessary provider status from relocating its facility if it moves no more than 250 yards from the existing location, unless it can demonstrate that its construction plans began prior to December 8th, 2003.

We believe this arbitrary distance requirement will do great harm to CAHs and rural communities in Arkansas. It will force communities to choose between remaining in and maintaining older hospital facilities (which will most likely cost Medicare more, not less, over time because the higher costs of operating in an outdated building more than offset the cost of rebuilding), or building new hospitals and losing their CAH status. Neither choice is acceptable.

When CMS originally allowed states the authority to designate hospitals as medically necessary and waive the 35-mile CAH limit, it was for all the right reasons. Yet, with the mere stroke of a pen, CMS could tag those hospitals as no longer necessary for all the wrong reasons.

The Arkansas Hospital Association objects to the Rule's change regarding CAHs and asks that CMS delete it.

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CMS-1500-P-343

Date: 06/14/2005

CAH/Reloc

Hefter
Hartstein
Collins
Morey
Smith

Submitter : Mr. Bill Boswell

Organization : McCamey County Hospital District

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

As members of the House Rural Health Care Coalition we write to state ourour opposition to the proposed construction ban on the vast majority of Critical Access Hospitals (CAH) in our states and across America.

As you know, the federal critical access program allows rural hospitals to receive reimbursements from the Centers for Medicare and Medicaid Services (CMS) at 101% of their cost rather than using the prospective payment program. Rural hospitals are eligible for the programs if they have 25 or fewer acute-care beds, have an average length of stay less than 96 hours, and are located at least 35 miles from another hospital. As communities around the country will attest, CAH has literally been a lifesaving designation for rural towns.

The proposed regulation transfers CMS control over the basic structure of local rural health care, an unprecedented loss of control that would threaten all hospital in all communitites. This regulation would require a provider move no more than 250 yards from the existing location, unless it can demonstrate that its construction plans began prior to December 8, 2003. We believe this arbitrary designation will do great harm to CAHs and rural communities.

Rural hospitals will lose CAH status and be forced to revert back to the prospective payment system, thereby halting development plans. In many instances, rural institutions are located on small campuses in the middle of residential neighborhoods with no room to expand. Relocation proves to be the most appropriate, and sometimes the only, alternative. Ironically, the CMS proposal will cost Medicare more, not less, over time because the higher costs of operating in an outdated building more than offset the cost of rebuilding.

We would be pleased to be part of any discussion to assist in the resolution of this issue.